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Supreme Court, U.S.
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No. 07-917

IN THE

Supreme Court of the United States

APOTEX, INC. and APOTEX CORPORATION,

Petitioners,

v.

ABBOTT LABORATORIES,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Federal Circuit, in direct conflict with long-established precedent of this Court, erred in upholding the district court's imposition of contempt remedies on Apotex while simultaneously holding that the district court abused its discretion in finding Apotex in contempt of a prior injunction.

LIST OF PARTIES

TorPharm, Inc., (now subsumed within Apotex, Inc.) an original plaintiff below, no longer exists.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parent company of Apotex, Inc. is Apotex Pharmaceutical Holdings, Inc. The parent company of Apotex Corp. is Apotex Holdings, Inc. There is no publicly-held corporation that owns 10% or more of either Apotex, Inc. or Apotex Corp.

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OPINIONS BELOW

The decision of the United States Court of Appeals for the Federal Circuit (App. A)[1] for which review is sought is available at 503 F.3d 1372 (Fed. Cir. 2007). The decision of the United States District Court for the Northern District of Illinois that was reviewed by the Federal Circuit (App. B) is reported at 455 F. Supp. 2d 831 (N.D. Ill. 2006).

JURISDICTION

The Federal Circuit issued the judgment for which review is sought on October 11, 2007. The Federal Circuit denied Apotex's petition for rehearing en banc on December 5, 2007. (App. C). This Court has jurisdiction to review the judgment of the Federal Circuit under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves sections of the Hatch-Waxman Act, which amended the Patent Laws, 35 U.S.C. § 1 *et seq.*, particularly 35 U.S.C. § 271(e) (App. D), and the Food, Drug and Cosmetic laws, 21 U.S.C. § 1 *et seq.*, particularly 21 U.S.C. § 355, governing Abbreviated New Drug Applications ("ANDAs") for pharmaceutical products.

STATEMENT OF THE CASE

The issue before this Court is whether district courts are authorized to use contempt proceedings to issue binding factfindings, injunctions, remedies and

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1. References to "App. ___" are to the Appendices attached hereto, as required under Supreme Court Rule 14.1(i).

judgments, absent an arguable act of contempt in the first instance. This issue has considerable significance in patent cases, particularly Hatch-Waxman cases involving drug products, where Congress has strongly incentivized generic drug companies to design around brand name patents to bring cheaper drugs to market before patents expire.

This Hatch-Waxman case involves a decade-long patent dispute between Abbott Laboratories and TorPharm, Inc. (now part of Apotex, Inc.) involving drugs generically called "divalproex sodium." In 2004, Judge Richard A. Posner, sitting by designation in the district court, entered an injunction prohibiting Apotex from commercially manufacturing, using, selling or offering to sell infringing divalproex sodium in the United States, and further prohibiting FDA from approving TorPharm's divalproex sodium ANDA No. 75-112.

The present petition is directed towards post-judgment proceedings that Abbott initiated before Judge Posner in August of 2006. The Federal Circuit acknowledged that the Apotex activities Abbott complained of—serving as a divalproex sodium contract manufacturer for a different ANDA filer, Nu-Pharm—did not violate Judge Posner's 2004 injunction. The Federal Circuit held that Judge Posner abused his discretion in holding Apotex in contempt. The Federal Circuit nevertheless refused to vacate Judge Posner's new infringement factfindings regarding the Nu-Pharm ANDA, and a new injunction prohibiting Apotex from commercially making this second ANDA product, and prohibiting FDA from approving this second ANDA. Apotex thus is subject to contempt punishments despite doing nothing in contempt of a court order.

The dissent from the panel's decision called the Federal Circuit's refusal to vacate Judge Posner's contempt remedies regarding the second ANDA "puzzling," and it truly is. If the Federal Circuit was convinced that Apotex did nothing in contempt, Apotex should not be bound by the contempt punishment (infringement findings and a new injunction) that Judge Posner imposed.

Since the Federal Circuit now has established a rule granting district courts the authority to impose contempt remedies *without* an act in contempt of a court order, litigants have a powerful incentive to avoid regular district court actions, with the traditional jurisdictional and procedural protections they offer defendants. Indeed, Abbott did so here. Before initiating the August 2006 proceedings before Judge Posner, Abbott had already sued Nu-Pharm and Apotex in the Northern District of Illinois alleging that the divalproex sodium drug in the Nu-Pharm ANDA infringed Abbott's patents.

Review is needed here because the Federal Circuit's refusal to vacate the factfindings and injunction order against Apotex from the contempt proceedings directly conflicts with precedent from this Court.

Further, permitting the Federal Circuit's rule to stand as a lone minority position will work a tremendous disservice on a unique area of patent law—the goal of encouraging adjudged infringers to try to design-around patents and bring new products to market. This Court has long-recognized that federal policy favors "the full and free use of ideas in the public domain." *Lear, Inc. v. Adkins*, 395 U.S. 653, 674 (1969) The public interest on

that score is particularly heightened here, since Congress enacted the Hatch-Waxman act with the express purpose of encouraging generic drug companies to challenge brand-name drug companies' patents. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-678 (1990). If a second generic challenge may be routed to contempt proceedings, the Congressional intent of Hatch-Waxman will be permanently undermined.

Apotex respectfully requests that this Court clarify that when a party's post-injunction activities do not violate any court order, a patentee must complain of these new acts in a new case. New or expanded remedies should not be imposed on a party via contempt proceedings unless that party is first in actual contempt of a court order. Similarly, when a contempt finding is reversed, any findings, injunctions, remedies and/or judgments issued during the contempt proceedings must be vacated.

To demonstrate why Apotex should never have been the subject of contempt proceedings, let alone subject to new infringement findings and injunctions from Judge Posner, requires a brief overview of the prior patent case and related decisions.

I. *TorPharm I.*

In about April, 1997, TorPharm, Inc. (now part of Apotex, Inc.) submitted an ANDA to FDA seeking approval to market generic Depakote®, an anti-epileptic drug marketed by Abbott. TorPharm's ANDA contained a "Paragraph IV certification" stating that Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 ("the Abbott patents"), were not infringed, invalid, and/or unenforceable. *Abbott Labs. v. TorPharm, Inc.*, 156

F. Supp. 2d 738, 740 (N.D. Ill. 2001) (*"TorPharm I"*). Abbott relied on TorPharm's Paragraph IV ANDA filing to sue TorPharm (and Apotex) for infringement of the patents under 35 U.S.C. § 271(e)(2)(A). *Id.*

The Abbott patents are directed toward a particular form of the drug divalproex sodium. "Divalproex sodium" means the drug contains two valproate molecules for every one sodium atom. Abbott claimed to have discovered a unique form of divalproex sodium, namely one that was oligomeric, made up of 4, 5, or 6 divalproex sodium units.

TorPharm disputed that its drug product was oligomeric, particularly since Abbott based its oligomer structure theory on inferences from solution-based molecular-weight testing, not through direct proofs by single-crystal testing on the solid.

The district court (Norgle, J.) initially entered summary judgment of infringement against the TorPharm ANDA. The district court concluded that Abbott's molecular-weight tests were enough to prove TorPharm's product satisfied the oligomer elements. *TorPharm I*, 156 F. Supp. 2d at 746.

II. *TorPharm II.*

On appeal, the Federal Circuit reversed the infringement conclusion because there was a fact dispute whether TorPharm's product satisfied the "oligomer" element. *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1377 (Fed. Cir. 2002) (*"TorPharm II"*). The court noted that while one might rely on Abbott's solution-based molecular-weight tests to infer the presence of an oligomer, a factfinder could also find such tests insufficient to prove

the structure of TorPharm's divalproex sodium as a solid. *Id.* The case was thus remanded to the district court for trial. *Id.* at 1380-81.

III. *TorPharm III.*

After remand, Judge Posner was designated to sit as a district court judge for the case. After trial, Judge Posner issued an opinion finding infringement. *Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043, 1054 (N.D. Ill. 2004) (*"TorPharm III"*). Judge Posner observed that divalproex sodium could exist as a noninfringing monomer, infringing oligomer, or noninfringing polymer. *Id.* at 1045-46. He explicitly found that the "only *certain* way to determine" whether a given divalproex sodium structure was infringing or not was single-crystal x-ray testing. *Id.* at 1049 (emphasis in original). Judge Posner relied on Abbott's solution-based molecular-weight testing to infer that TorPharm's product was oligomeric.

At the conclusion of the trial, Judge Posner enjoined TorPharm, Inc., Apotex, Inc. and Apotex Corp. from infringing the Abbott patents, and ordered FDA to postpone final approval of the TorPharm ANDA until the expiration of the Abbott patents. *Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831, 833 (N.D. Ill. 2006) (*"Abbott V"*).

To date, FDA has not finally approved the TorPharm ANDA.

IV. *TorPharm IV.*

TorPharm appealed Judge Posner's findings. The Federal Circuit summarily affirmed his judgment. *Abbott Labs. v. TorPharm, Inc.*, 122 Fed. Appx. 511 (Fed. Cir. 2005) (*"TorPharm IV"*). Abbott received the only

remedy it had requested, and indeed, the only one the statute permitted: an injunction ordering postponement of final FDA approval of the TorPharm ANDA until the Abbott patents expired. *See* 35 U.S.C. § 271(e)(4).

V. Apotex's subsequent design-around efforts.

The prior decisions of the Federal Circuit and Judge Posner provided a clear design-around path. *TorPharm II*, 300 F.3d at 1377; *TorPharm III*, 309 F. Supp. 2d at 1045-46. A divalproex sodium "polymer" could not infringe. Single-crystal X-ray diffraction testing would be "certain" proof of a noninfringing structure. *TorPharm III*, 309 F. Supp. 2d at 1049. Abbott's own representations to the PTO during the prosecution of the patents-in-suit, and the trial testimony of its expert, gave direction how one could prepare noninfringing divalproex sodium products.

Apotex developed two new processes for preparing divalproex sodium to maximize its ability to prepare a noninfringing product. All such development activities occurred in Canada. The new divalproex sodium products were used to conduct a new human biostudy, formulation, and stability studies (again, in Canada), and eventually submitted to FDA as an entirely new ANDA.

Although Apotex developed the new divalproex sodium, there were several practical constraints on what it could do with it. The pending injunction created uncertainty. The market was shrinking since other generic competitors were on the horizon. The patents were near the end of their life. Abbott was trying to switch patients over to a new extended-release formulation; Apotex's attempt to make a generic version of that new formulation had failed. Apotex had

committed its manufacturing facilities to drugs involved in patent challenges that involved potentially a billion-dollar return.

To recoup its R&D costs, Apotex gave the opportunity to pursue U.S. rights for the new products to Nu-Pharm, Inc. Nu-Pharm focuses on sales and marketing of drug products, not production. Apotex had a longstanding relationship with Nu-Pharm, having once been owned by Apotex's parent company. Nu-Pharm already sold Apotex's divalproex sodium in Canada, and thus was familiar with the product. The parties agreed that if Nu-Pharm took on the R&D costs and the litigation efforts with Abbott, Apotex would manufacture the new products in Canada.

VI. Events leading to the second district court proceeding, involving Nu-Pharm.

A. Nu-Pharm's ANDA filing.

On March 7, 2005, Nu-Pharm filed a divalproex sodium ANDA with FDA. The ANDA clearly identifies Nu-Pharm as the ANDA sponsor; Apotex, Inc. as the contract manufacturer in Canada; and Apotex Corp. as the correspondence address. Nu-Pharm filed a Paragraph IV certification with its ANDA, consistent with its independent assessment that the Apotex design-around products were not infringing oligomers.

B. Abbott knew precisely what Nu-Pharm was.

Nu-Pharm was no stranger to Abbott. Abbott had previously accused Nu-Pharm's Canadian divalproex sodium product—a product that Abbott knew Apotex made for Nu-Pharm—of infringing the Canadian equivalent to the Abbott patents. *See Abbott Labs. Ltd.*

v. Nu-Pharm Inc., No. T-1722-95 [1998] 78 C.P.R.3d 38, 1998 Carswell Nat. 269 (Fed. Ct. Trial Div. Feb. 11, 1998) (acknowledging Apotex as Nu-Pharm's supplier); *rev'd*, [1998] 83 C.P.R.3d 441, 1998 Carswell Nat. 1904 (Fed. Ct. App. Sept. 28, 1998) (finding Nu-Pharm's noninfringement position valid). Indeed, during *TorPharm I*, Abbott sought detailed discovery of Nu-Pharm's Canadian divalproex sodium products. Abbott used the *TorPharm I* case specifically to elicit testimony about the relationship between Nu-Pharm and Apotex.

C. Abbott sues Nu-Pharm in a traditional Hatch-Waxman action.

After Nu-Pharm submitted its Paragraph IV notice letter to Abbott for the Nu-Pharm ANDA, Abbott initiated the Nu-Pharm litigation in the Northern District of Illinois, which was assigned to Judge Pallmeyer. Abbott's complaint asserted that the filing of the Nu-Pharm ANDA was an infringing act under 35 U.S.C. § 271(e), and sought an order enjoining final FDA approval of Nu-Pharm's ANDA until the Abbott patents expired. Abbott did not move to have its new case assigned to Judge Posner as a "related case." *See* N.D. Ill. Local Rule 40.4 (permitting reassignment of a case to a judge hearing an earlier-filed related case).

As a result of Abbott's suit, Nu-Pharm's 500 mg product was subject to a 30-month stay of FDA approval. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (suit filed by patentee within 45 days after Paragraph IV certification imposes automatic 30-month stay of final FDA approval). This meant that absent a district court decision in its favor, Nu-Pharm's ANDA product would not be finally approvable until 30 months from the date Abbott

received Nu-Pharm's Paragraph IV Notice letter, or about November 13, 2007. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa).

D. Nu-Pharm voluntarily disclosed its ANDA, product samples, and Apotex's involvement in 2005.

In 2005, months before Abbott propounded a single discovery request to Nu-Pharm, Nu-Pharm voluntarily turned over to Abbott's attorneys the entirety of the Nu-Pharm ANDA, and raw material and biobatch product samples. The ANDA identified Nu-Pharm as the ANDA sponsor and explicitly identified Apotex, Inc. as the contract manufacturer.

E. Abbott tries to pull Apotex into the Nu-Pharm litigation.

On January 25, 2006, Abbott moved to file an amended complaint in the Nu-Pharm litigation against Apotex, Inc. and Apotex Corp., alleging, among other things, that:

- Apotex, Inc. and Apotex Corp. were subject to Judge Posner's prior injunction;
- Apotex, Inc. was manufacturing the Nu-Pharm ANDA product, which Abbott alleged infringed the Abbott patents; and
- Apotex Corp. committed an act of infringement when it served as the registered agent for the Nu-Pharm ANDA.

Abbott moved to file a second amended complaint on February 17, 2006. In response, Apotex moved to dismiss Abbott's claims on the basis that Abbott's pleadings conceded that Nu-Pharm was the ANDA sponsor; that Apotex's allegedly infringing activities occurred outside the U.S.; and that Apotex's activities were immune from liability under the "safe harbor" provisions of 35 U.S.C. § 271(e)(1).

Abbott filed a third amended complaint on April 21, 2006, again seeking to bring Apotex, Inc. and Apotex Corp. as defendants into the Nu-Pharm litigation. Apotex filed yet another motion to dismiss Abbott's claims under FED. R. CIV. P. 12(b). That motion remains pending.

For more than a year, Abbott was content for its claims against the Nu-Pharm ANDA—including claims based on allegations that the Nu-Pharm ANDA product lacked colorable differences from the TorPharm ANDA product—to proceed before Judge Pallmeyer. Abbott never sought to return to Judge Posner via contempt proceedings or otherwise.

F. When Nu-Pharm provides Abbott with proof that divalproex sodium from Nu-Pharm is a noninfringing crystalline polymer, Abbott returns to Judge Posner.

1. The Nu-Pharm litigation moves into expert discovery.

Under Judge Pallmeyer's scheduling order, the parties were to exchange their first round of expert reports on July 31, 2006, with expert discovery to follow. Judge Pallmeyer also ordered Nu-Pharm to file its motion for summary judgment of noninfringement on

August 15, 2006, with Abbott's response due shortly thereafter.

On July 31, 2006, Nu-Pharm provided Abbott with the expert report of Prof. Michael Hursthouse, who heads the United Kingdom's national crystallography service, and is a world-renowned specialist in difficult-to-solve crystal structures. In the prior litigation, Abbott's expert Dr. Jerry Atwood had proclaimed that technologically, it was impossible to perform the "only certain" test of molecular structure, owing to the small size of TorPharm's divalproex sodium crystals. *TorPharm III*, 309 F. Supp. 2d at 1049-50. But, Nu-Pharm's Hursthouse analyzed the Nu-Pharm crystals using a specialized low-temperature analysis. He confirmed that this divalproex sodium was polymeric, not oligomeric—the very structure that the Federal Circuit and Judge Posner previously said could not infringe Abbott's patents. *TorPharm II*, 300 F.3d at 1377; *TorPharm III*, 309 F. Supp. 2d at 1046.

2. Based on the single-crystal x-ray data, Nu-Pharm moves for summary judgment of noninfringement.

Based on its single-crystal testing, which Judge Posner previously found was "certain" proof of molecular structure, *TorPharm III*, 309 F. Supp. 2d at 1049, Nu-Pharm moved for summary judgment of noninfringement before Judge Pallmeyer.

3. Faced with the new polymer evidence, Abbott retreats from the Nu-Pharm litigation, and returns to Judge Posner.

The same day Nu-Pharm filed its summary judgment motion, Abbott abruptly suspended its efforts before Judge Pallmeyer, and instead returned to Judge Posner's courtroom, filing what it termed a "Motion to Enforce Its Injunction Order." In its motion, Abbott did not contend that Apotex was violating Judge Posner's prior order. Instead, Abbott presented the same allegations against Nu-Pharm's product (it lacked colorable distinctions from the TorPharm ANDA product; Nu-Pharm and Apotex were scheming to avoid the injunction order; etc.) that it had complained of before Judge Pallmeyer. Abbott sought the same relief that it was seeking from Judge Pallmeyer: postponing final FDA approval of the Nu-Pharm ANDA product until the Abbott patents expire.

Abbott never moved under Local Rule 40.4 to have the *Nu-Pharm* litigation assigned to Judge Posner. *See* N.D. Ill. Local Rule 40.4. Instead, Abbott asked Judge Pallmeyer to stay the Nu-Pharm proceedings so that it could now proceed before Judge Posner. Abbott thus gained a critical advantage: keeping the Nu-Pharm Hatch-Waxman case pending before Judge Pallmeyer ensured that an adverse ruling from Judge Posner would not qualify as a court decision on the merits sufficient to terminate the automatic 30-month stay of FDA approval against Nu-Pharm. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa).

Abbott's motion before Judge Posner accused Apotex of violating Judge Posner's prior injunction, but failed to specify what Apotex's alleged infringing acts in violation were. Apotex confirmed that it was not making, using, selling or offering for sale or importing the TorPharm ANDA product that was the subject of the prior injunction.

Apotex, for its part, insisted that the pending Hatch-Waxman proceedings before Judge Pallmeyer served as the proper forum to adjudicate whether the Nu-Pharm ANDA product infringed the Abbott patents. Apotex further pointed out that the Hatch-Waxman remedies are ANDA-specific, and thus an injunction against one ANDA could not be expanded to cover future ANDA applications.

VII. After an irregular proceeding, Judge Posner "extends" his prior injunction against the TorPharm ANDA product to cover the Nu-Pharm ANDA product.

In response to Abbott's August 15, 2006 motion, Judge Posner never addressed Apotex's threshold question, *i.e.*, what Apotex had supposedly done that actually violated his prior injunction order. Judge Posner held an evidentiary hearing not to hear any evidence from Abbott that Apotex did the acts his prior order prohibited (commercial marketing of the TorPharm ANDA product). Instead, Judge Posner directed the entire hearing towards whether the new Nu-Pharm ANDA product infringed Abbott's patents.

Despite repeated pleas from Apotex, Judge Posner never ordered the production of expert reports; never permitted Apotex discovery of Abbott's experts or the

underlying test data; and refused to give Apotex time to submit comparative testing between the TorPharm and Nu-Pharm products that Judge Posner demanded. (App. E, 49a-52a). Indeed, when Apotex submitted with post-hearing briefing the comparative test data that Judge Posner deemed essential to his infringement decision—data that showed that the TorPharm and Nu-Pharm ANDA products *were not* the same—Judge Posner refused to consider it. The basis for that refusal was not that the evidence was irrelevant, or non-compliant with the evidentiary rules, but because he had not "authorized" Apotex to submit such evidence in its defense. *Abbott V*, 455 F. Supp. 2d at 837.

In his opinion, Judge Posner found that the Nu-Pharm ANDA product infringed Abbott's patents. The sole relief he granted was to "extend the injunction to embrace the Nu-Pharm ANDA." *Abbott V*, 455 F. Supp. 2d at 840. This is the same relief Abbott sought in the Nu-Pharm litigation before Judge Pallmeyer. Nowhere in Judge Posner's opinion did he identify any act by Apotex that actually violated his prior injunction order, such as commercially marketing the TorPharm ANDA product. Thus, Abbott secured new factfindings and a new injunction regarding infringement of the Nu-Pharm ANDA product, without ever presenting any evidence to Judge Pallmeyer, the Judge assigned to hear the case against Nu-Pharm.

In view of Judge Posner's decision, Judge Pallmeyer stayed the Nu-Pharm litigation; that stay is still in effect.

VIII. The Federal Circuit finds no contempt, but accepts Judge Posner's conclusion that Nu-Pharm's ANDA product would infringe the Abbott patents.

On October 11, 2007, the Federal Circuit unanimously held that a contempt finding was an abuse of Judge Posner's discretion since his 2004 injunction did not restrict the filing of an ANDA by Nu-Pharm, nor did it preclude Apotex from developing further divalproex sodium products outside the United States. But, as Judge Dyk explained in dissent, "The majority reaches a different conclusion by holding that contempt proceedings are appropriate as long as there is no more than a 'colorable difference' between the accused and enjoined products." *Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372, 1384 (Fed. Cir. 2007) (Dyk, J., dissenting) (*"Abbott VI"*). The panel was untroubled by Judge Posner's holding of contempt-style proceedings to issue new findings and remedies to extend his 2004 injunction to cover the new Nu-Pharm ANDA. *Id.* at 1381. Judge Dyk disagreed with the majority saying, "If I am correct that contempt proceedings were improper, it necessarily follows that any decisions made in the course of those proceedings must be vacated." *Id.* at 1384 (Dyk, J., dissenting).

Ultimately, the Federal Circuit refused to rehear the appeal en banc.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's refusal to vacate the district court's new findings and injunction directly conflicts with this Court's prior precedent.

This case raises serious due process concerns and cannot be squared with this Court's decision in *California Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609 (1885).

In *California Artificial Stone*, the patentee had previously successfully proven that pavement blocks the defendant manufactured infringed his patent; the defendant was enjoined from making such pavement in the future. 113 U.S. at 612-13. The defendant then changed his process for constructing pavement; the patentee initiated contempt proceedings against the defendant. *Id.* at 613. While the district court found contempt, the court of appeals reversed. *Id.*

This Court characterized the patentee's complaint regarding the construction of the new pavement as "substantially a new suit on the patent; and we are asked to decide it." *Cal. Artificial Stone*, 113 U.S. at 617. It instructed that since "the judges disagree there can be no judgment of contempt; and the defendant must be discharged." *Id.* at 618. Because it was "a doubtful question whether the new process adopted is an infringement or not," the "by far . . . most appropriate" approach was for the patentee to bring an independent infringement suit regarding the new pavement. *Id.* The "[p]rocess of contempt is a severe remedy, and should not be resorted to where there is fair ground of doubt as to the wrongfulness of the defendant's conduct." *Id. accord Preemption Devices, Inc. v. Minn. Mining & Mfg. Co.*, 803 F.2d 1170, 1173 (Fed. Cir. 1986).

The Federal Circuit ignored the principles set forth in *California Artificial Stone* by letting Judge Posner's new infringement findings and injunction against Apotex and the Nu-Pharm ANDA stand, even though the Federal Circuit expressly found Apotex never violated the 2004 injunction.

A. It was undisputed that Apotex did not violate the 2004 injunction.

It is undisputed that Apotex did not violate the 2004 injunction. The Federal Circuit recognized, quite correctly, that "[s]ince Apotex did not make, use, sell, offer to sell in the U.S. or import into the U.S. generic divalproex sodium, it did not violate the injunction." *Abbott VI*, 503 F.3d at 1382. The panel majority further confirmed that filing the Nu-Pharm ANDA was not an act that "actually violated the original injunction." *Id.* The "plain language" of the original injunction only prohibited FDA from approving the TorPharm ANDA. *Id.* at 1383. By statute, Congress immunized from infringement liability all activities Apotex engaged in to assist Nu-Pharm with filing the Nu-Pharm ANDA. *See* 35 U.S.C. § 271(e)(1).

There similarly was no dispute that the district court never intended to hold Apotex in contempt for the second Nu-Pharm ANDA filing. *See Abbott VI*, 503 F.3d at 1382. Abbott realized that such authority was wanting; it never asked for any finding or monetary award for any purported contempt. ("THE COURT: ... you're not actually asking me to find Apotex in contempt, is that correct? MR. REIDY: That's correct, Judge."). Likewise, Judge Posner realized he had no contempt authority, and stated in open court that he had no intention of entering

a contempt finding. ("So, my legal question is whether I have to find by clear and convincing evidence that these are the same products, *even though I'm not actually going to find contempt or enter a contempt sanction.*") (emphasis added). (App. E, 53a). The Federal Circuit explicitly held that the district court "abused its discretion in holding Apotex in contempt," *Abbott VI*, 503 F.3d at 1382, reversing any "judgment of contempt" that Judge Posner arguably entered. *Id.* at 1383.

Apotex submits that without a violation of an injunction, and without the authority to hold a party in contempt, there was no legal basis to nevertheless uphold the contempt remedies Judge Posner imposed as punishment to Apotex involving the second Nu-Pharm ANDA. Under the Federal Circuit's own reasoning, there was *no* wrongful conduct by Apotex in violation of the injunction. *Abbott VI*, 503 F.3d at 1382. Thus, as Judge Dyk cogently observed in dissent, there was at the very least "a fair ground of doubt" as to the alleged wrongfulness of Apotex's conduct. *Id.* at 1383 (Dyk, J., dissenting); *KSM Fastening Sys., Inc. v. H.A. Jones Co., Inc.*, 776 F.2d 1522, 1524 (Fed. Cir. 1985) ("A civil contempt proceeding for violation of an injunction issued after patent litigation, while primarily for the benefit of the patent owner, nevertheless, involves also the concept of an affront to the court for failure to obey its order"). Accordingly, as *California Artificial Stone* requires, the Federal Circuit should have exercised restraint and vacated Judge Posner's "contempt" remedies against Apotex.

The Federal Circuit chose not to vacate Judge Posner's findings and injunction under the theory that the second Nu-Pharm product was insubstantially different from the original infringing product. *Abbott VI*,

503 F.3d at 1380, n.3. Respectfully, the Federal Circuit should not have even begun that analysis without first finding the existence of an injunction order that prohibited any of Apotex's acts. Even so, the only way Judge Posner could find "no evidence" that the TorPharm and Nu-Pharm products were different was because Judge Posner struck as "unauthorized" Apotex's side-by-side comparison test data that proved those differences! Thus, the irregular proceedings wreaked an injustice on Apotex.

Prior cases before this Court, and in every other circuit, traditionally vacate the contempt remedies when a party is not in contempt; when the contempt proceedings were irregular; or when the incorrect rule of law was applied to render the contempt analysis. For example:

In *California Artificial Stone*, this Court ordered dismissed the patent infringement charges against the defendant when contempt was not reliably shown. 113 U.S. at 618.

In *Cooke v. United States*, 267 U.S. 517, 539-40 (1925), an attorney's letter to the district court was viewed as contemptuous; nevertheless, owing to the irregularity of the contempt proceedings themselves, the contempt punishment was vacated and the case remanded for further proceedings.

In *Ex parte Fisk*, 113 U.S. 713 (1885), when a state court lacked jurisdiction over Fisk, its order finding him in contempt was similarly "without jurisdiction and void." *Id.* at 726. *Also see United Elec., Radio and Mach. Workers of Am. v. 163 Pleasant St. Corp.*, 960 F.2d 1080 (1st Cir. 1992) (vacating preliminary injunction and

contempt order when district court lacked personal jurisdiction over Scottish defendant corporation).

In *Hicks v. Feiock*, 485 U.S. 624 (1988) this Court vacated the contempt order after determining the correct application of the Due Process clause, remanding for further proceedings.

In *Fonar Corporation v. Deccaid Services, Inc.*, 983 F.2d 427 (2d Cir. 1993), the Second Circuit vacated contempt findings when it found that the alleged copyright infringement did not violate a prior court order.

In *United States v. Spectro Foods Corporation*, 544 F.2d 1175 (3rd Cir. 1976), the Third Circuit vacated contempt judgments and remedies in connection with a TRO issued for violating FDA regulations, because the "right to remedial relief disappears when it is determined that an injunction was issued erroneously." *Id.* at 1182.

In *Imageware, Inc. v. U.S. West Communications*, 219 F.3d 793 (8th Cir. 2000), the Eighth Circuit vacated a contempt judgment and associated remedies when it found that there was no underlying act of contempt.

Also see Proctor v. North Carolina, 830 F.2d 514 (4th Cir. 1987) (vacating factfindings and remedy when district court's contempt ruling was in error); *Karaha Bodas Co., v. Perusahaan Pertambangan Minyak Dan Gas Bumi Negara*, 335 F.3d 357 (5th Cir. 2003) (vacating contempt order and preliminary injunction); *Collins v. Barry*, 841 F.2d 1297 (6th Cir. 1998) (vacating contempt findings and injunctions); *Ferrell v. U.S. Department of Housing & Urban Development*, 186 F.3d 805 (7th Cir.

1999) (vacating contempt citation and preliminary injunction); *Federal Trade Commission v. Enforma Natural Products*, 362 F.3d 1204 (9th Cir. 2004) (vacating injunction from contempt proceedings); *Federal Trade Commission v. Kuykendall*, 371 F.3d 745 (10th Cir. 2004) (vacating contempt remedies for party held not in contempt); *Doe v. Bush*, 261 F.3d 1037 (11th Cir. 2001) (vacating contempt order and class certification order); *Shepherd v. American Broadcasting Cos.*, 62 F.3d 1469 (D.C. Cir. 1995) (vacating district court factfindings after reversing contempt sanctions).

The reason why contempt remedies are routinely vacated in conjunction with a finding of no contempt is fundamental: a party should not be punished in contempt without first correctly finding a predicate contemptible act. There is no excuse for exempting patent cases from this sound principle.

B. The district court had no "inherent authority" to enforce an injunction that was never violated.

While the Federal Circuit was correct that a district court has inherent authority "to enforce its injunction through contempt proceedings," *Abbott VI*, 503 F.3d at 1379, by its own reasoning, there was nothing to enforce here since the injunction did not cover the activity complained of. Apotex did nothing to justify contempt.

The Federal Circuit acknowledged that "we cannot and do not purport to rewrite the original injunction." *Abbott VI*, 503 F.3d at 1383. Yet it paradoxically sustained the district court's use of contempt proceedings to do just that, namely expand the injunction to forbid FDA from approving the Nu-Pharm ANDA. *Id.* With the

contempt proceedings themselves in error, "it follows that the remedies imposed based on the finding of infringement must be vacated." *Id.* at 1385 (Dyk, J., dissenting); *also see Perez v. Danbury Hosp.*, 347 F.3d 419 (2nd Cir. 2003) (since district court's later injunction from contempt proceedings was not designed to ensure compliance with consent decree, but to expand its terms and impose new obligations beyond the original order, it was improper and vacated).

The proper route to the remedy the district court provided—precluding FDA from approving the second Nu-Pharm ANDA—was the Hatch-Waxman lawsuit that Abbott already had filed under 35 U.S.C. § 271(e), which Abbott cut short upon receiving Nu-Pharm's evidence establishing noninfringement. *See Abbott VI*, 503 F.3d at 1384 (Dyk, J., dissenting); *Cal. Artificial Paving*, 113 U.S. at 618. If Abbott thought it had evidence sufficient to foreclose a trial, it was free to seek summary judgment, but that would be the most "summary" procedure to which it would be entitled, and even that remedy would be unavailable if material facts were in dispute. *See* FED. R. CIV. P. 56.

* * *

If the district court's findings and injunction order is not vacated, then the Federal Circuit's reversal of the contempt finding against Apotex is mere lip service, for Abbott is receiving precisely the remedy it sought against Apotex (infringement findings and an expanded injunction) from Judge Posner.

There is no justification for imposing contempt proceedings and remedies in patent cases absent a threshold finding of contempt. In fact, as the next section

discusses, such a rule fundamentally undermines Congressional incentives set in place by Hatch-Waxman to encourage generic drug manufacturers to challenge brand-name drug patents.

II. The Federal Circuit's decision creates a loophole that undermines both Congressional intent and the public interest in encouraging patent design-around efforts.

Patents are, in essence, a tradeoff that the public has made to balance the evil of monopoly against the good of new inventions. Because monopolies are rightly viewed with suspect, the patent law has always strongly encouraged competitors to design-around patents to bring new products to market. *Westvaco Corp. v. Int'l Paper Co.*, 991 F.2d 735, 745 (Fed. Cir. 1993); *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991); *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235-36 (Fed. Cir. 1985); *also see Lear*, 395 U.S. at 670 (acknowledging the "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain").

Because a patent challenge by a would-be competitor is the surest way to ensure that the public is not continually "required to pay tribute to would-be monopolists without need or justification," this Court has previously rejected the imposition of heightened requirements on patent challenges that would muzzle "the only individuals with enough economic incentive to challenge" patents. *Lear*, 395 U.S. at 670.

Indeed, the very impetus for the Hatch-Waxman Act that created the ANDA process, and created a specific avenue for challenges to brand-name patents, and the

remedies available, was to encourage generic drug companies to bring lower-cost drugs to market, fast. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2001); *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002).

A generic drug challenge requires a tremendous investment, not only with regard to the drug itself, but ensuring that a given drug can be prepared as a viable formulation, capable of achieving the correct therapeutic performance, in facilities that pass FDA standards. It may well be that the only party with the capabilities and resources to design-around a brand name drug patent is a party that previously tried to do so and failed. Moreover, patent litigation and the associated liability is not without its costs. *See Medimmune, Inc. v. Genentech, Inc.*, 127 S. Ct 764, 775 (2007) ("The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III").

It is hardly surprising that generic drug companies' efforts to challenge brand-name patents, either on validity or on infringement, will sometimes fail. But Congress also included provisions within Hatch-Waxman that would encourage further attacks on brand-name patents. These provisions include:

- Immunizing from infringement liability all activities needed to develop a drug to submit an ANDA for review by FDA, in 35 U.S.C. § 271(e)(1);

- Permitting challenges to brand-name patents before a drug product is actually brought to market, under 35 U.S.C. § 271(e)(2); and
- Limiting by statute the permissible scope of remedies that a district court may award after an unsuccessful patent challenge (before the generic product comes to market) to *only* an injunction against infringing commercial activity in the U.S., and prohibiting FDA from finally approving the ANDA that was the subject of the lawsuit. 35 U.S.C. § 271(e)(4).

These statutory provisions are specifically designed to permit a generic drug company to mount multiple challenges to a brand name patent.

Under the Federal Circuit's decision in this case, if a generic drug company fails in its first attempt to avoid a brand-name patent, it loses the procedural protections that it would otherwise enjoy in a Hatch-Waxman patent infringement action for a subsequent design-around attempt. A patentee can first bring a traditional Hatch-Waxman infringement action (as Abbott did here), sticking a generic company with an automatic 30-month stay of FDA approval, 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa), and simultaneously initiate contempt proceedings, choosing at its leisure which forum will be most advantageous.

This gives brand-name patentees an unparalleled tactical advantage. The Federal Circuit recognized it as "substantial," *KSM*, 776 F.2d at 1524, and the consequent detriment to accused infringers seeking to design around a patent:

> Allowing the patentee to proceed by a summary contempt proceeding in all cases would unnecessarily deter parties from marketing new devices that are legitimately outside the scope of the patent in question.

Id. at 1530 (internal citations omitted).

These advantages will necessarily counsel against a second design-around attempt—a result that is in stark conflict with the purpose of the Hatch-Waxman Act, and ultimately detrimental to the drug-buying public, which might otherwise have a less expensive, competitive drug product available in the market.

CONCLUSION

The petition for certiorari should be granted. Alternatively, the Court should call for the views of the Solicitor General.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED OCTOBER 11, 2007

UNITED STATES COURT OF APPEALS FEDERAL CIRCUIT

No. 2007-1019.

Oct. 11, 2007.

ABBOTT LABORATORIES,

Plaintiff-Appellee,

v.

TORPHARM, INC., Apotex, Inc., and Apotex Corporation,

Defendants-Appellants.

Before MICHEL, Chief Judge, DYK, Circuit Judge, and OTERO, District Judge.*

Opinion for the court filed by MICHEL, Chief Judge. Opinion concurring-in-part and dissenting-in-part filed by DYK, Circuit Judge.

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* Honorable S. James Otero, District Judge, United States District Court for the Central District of California, sitting by designation.

Appendix A

MICHEL, Chief Judge.

This appeal involves the parties' ongoing dispute over the efforts of TorPharm, Inc., Apotex, Inc., and Apotex Corporation (collectively, "Apotex") to market a generic version of Depakote®, an anti-seizure medication containing divalproex sodium patented, produced, and sold by Abbott Laboratories ("Abbott"). Apotex now appeals from a final judgment of the United States District Court for the Northern District of Illinois holding Apotex in contempt for violating an injunction barring it from commercially manufacturing, using, selling, offering to sell, or importing into the United States generic divalproex sodium infringing Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 until their expiration. *Abbott Labs. v. Apotex, Inc.*, 455 F.Supp.2d 831, 840 (N.D.Ill.2006) ("*Abbott V*"). The charged conduct was the filing of a repetitive Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"). We uphold the district court's decision to entertain a contempt proceeding as well within its discretionary authority. However, because the district court erred in finding Apotex in contempt when the conduct at issue was not within the express terms of the injunction, we reverse the district court's judgment of contempt.

Appendix A

I.

This is the third time the parties are before us, and a brief history of the facts is warranted. In 1997, Apotex[1] filed ANDA No. 75-112 ("the Apotex ANDA") under the provisions of The Drug Price Competition and Patent Term Restoration Act, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), seeking FDA approval to manufacture and sell a generic version of Depakote®. The active ingredient of Depakote® is divalproex sodium. Abbott owns two patents directed to divalproex sodium: U.S. Patent Nos. 4,988,731 and 5,212,326 (collectively, the "Abbott patents"). The claims of the Abbott patents recite an oligomer containing about 4 to 6 repeating units of divalproex sodium. In its ANDA, Apotex certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the Abbott patents are invalid.

Abbott responded by filing suit against Apotex for patent infringement under 35 U.S.C. § 271(e)(2)(A). The district court granted summary judgment in favor of Abbott on both validity and infringement. *Abbott Labs. v. Torpharm, Inc.*, 156 F.Supp.2d 738 (N.D.Ill.2001) ("*Abbott I*"). On appeal, this court affirmed the ruling on validity but remanded for a trial on infringement. *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367 (Fed.Cir.2002) ("*Abbott II*"). We held that, when making

1. Apotex absorbed TorPharm subsequent to Abbott's suit in 1997. For purposes of this opinion, we simply refer to TorPharm, Inc. as "Apotex."

all reasonable inferences in favor of Apotex, a genuine issue of material fact was raised by the evidence as to whether Apotex's product was an oligomer having about 4 to 6 repeating units as required by Abbott's claims. *Id.* at 1376-77.

On remand, Judge Posner of the United States Court of Appeals for the Seventh Circuit, sitting by designation in the United States District Court for the Northern District of Illinois, conducted a bench trial, then concluded that Apotex's filing of the Apotex ANDA infringed the claims of the Abbott patents because Abbott's claims read on the product that was the subject of the Apotex ANDA. *Abbott Labs. v. TorPharm, Inc.*, 309 F.Supp.2d 1043 (N.D.Ill.2004) ("*Abbott III*"). In that case, the district court found that "Abbott proved by a preponderance of the evidence that Apotex's product is an oligomer of 4 to 7[sic] units of divalproex sodium and therefore infringes Abbott's patent." *Id.* at 1054. Accordingly, the district court entered the following injunction:

> TorPharm, Inc., Apotex, Inc., Apotex Corp., and their respective affiliates, successors in interest, and assigns are enjoined from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing within the United States, or from importing such product into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received

> final approval from FDA to market generic divalproex sodium.
>
> The effective date of any approval by FDA of ANDA No. 75-112, or any other application concerning defendants' generic divalproex sodium which the Court has found to be infringing, shall be no earlier than January 29, 2008, the date of expiration of Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326.

Abbott Labs. v. Torpharm, Inc., No. 97 C 7515, Injunction Order (N.D.Ill. Apr. 1, 2004).

Apotex appealed the district court's judgment of infringement and the injunction, which this court affirmed without opinion following oral argument. *Abbott Labs. v. Torpharm, Inc.*, 122 Fed.Appx. 511 (Fed.Cir.2005) ("*Abbott IV*").

Apotex, according to its evidence, then attempted to design around Abbott's patent claims and allegedly developed divalproex sodium in the form of a polymer which differs from an oligomer in that the polymer is made up of much more than about 4 to 6 repeating units of divalproex sodium. Rather than file a new ANDA itself, however, Apotex entered into an informal agreement with Nu-Pharm, Inc. ("Nu-Pharm") whereby Apotex would pay for costs associated with preparation of a new ANDA filing but NuPharm would take on what

Apotex characterizes as the "litigation risks" arising from such a filing.[2]

On March 7, 2005, Nu-Pharm filed ANDA No. 77-615 ("the Nu-Pharm ANDA") under 21 U.S.C. § 355(j) seeking FDA approval to manufacture and sell a 500 mg divalproex sodium product. Nu-Pharm made a paragraph IV certification that its product did not infringe the claims of the Abbott patents. Abbott filed a complaint for patent infringement under 35 U.S.C. § 271(e)(2)(A) against Nu-Pharm in the Northern District of Illinois on June 24, 2005, alleging that the Nu-Pharm ANDA also infringed the Abbott patent claims. The case was routinely assigned to District Judge Pallmeyer. In March 2006, Nu-Pharm filed an amended ANDA seeking FDA approval of 125 mg and 250 mg divalproex sodium products. Shortly thereafter, on May 3, 2006, Abbott filed a second section 271(e)(2)(A) action for patent infringement, this time against both Nu-Pharm and Apotex, who Abbott apparently had just learned were acting in concert. In its complaint, Abbott alleged that Apotex was the true party in interest behind the Nu-Pharm ANDA and the product described therein. The case, also filed in the Northern District of Illinois, was assigned in the normal course to District Judge Guzman. Upon motion by Abbott, the latter action was reassigned for "related case" treatment before Judge Pallmeyer.

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2. Prior to 1998, Nu-Pharm and Apotex were commonly owned by Apotex's parent company. From September 1998 onward, however, Nu-Pharm and Apotex allegedly had no corporate relationship.

Appendix A

On August 15, 2006, Nu-Pharm moved before Judge Pallmeyer for summary judgment of noninfringement of the Abbott patent claims. The same day, Abbott filed a "Motion to Enforce Its Injunction Order" before Judge Posner (still sitting by designation in the Northern District of Illinois in the original case), and filed a motion to stay the proceedings before Judge Pallmeyer. Judge Pallmeyer, after ordering two continuations, granted the stay on October 16, 2006.

Meanwhile, contempt proceedings continued before Judge Posner, who issued a decision on October 6, 2006 finding Apotex in contempt for violating the injunction issued in *Abbott III*. *Abbott V*, 455 F.Supp.2d at 840. After first confirming the district court's authority to enforce its own injunctions, Judge Posner characterized the injunction as extending to "any 'generic divalproex sodium' manufactured by Apotex that has been 'found to be infringing.' " *Id.* at 835. He then found that there was no difference between Apotex's old product and its new product (let alone a "colorable" difference), and that, based upon the evidence presented by the parties, Apotex's "new" product would infringe the claims of the Abbott patents. *Id.* at 837, 839. Accordingly, on October 6, 2006, the district court "extend[ed] the injunction to embrace" the Nu-Pharm ANDA. Specifically, the expanded injunction prohibited Apotex from:

> commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing, including divalproex sodium products

> synthesized using the processes employed in connection with ANDA No. 77-615, within the United States, or from importing such products into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received final approval from FDA to market generic divalproex sodium.

Id. at 840. No sanctions were imposed. Instead, the district court stated that should the violation continue, Apotex "will be risking heavy sanctions for its willful disobedience of the injunction." *Id.*

Final judgment was entered on October 10, 2006 against Apotex. This appeal followed. This court has jurisdiction to review the appeal under 28 U.S.C. § 1295(a)(1).

II.

A

On appeal, Apotex argues that the contempt proceeding was beyond the district court's statutory authority because the Hatch-Waxman Act does not itself grant a district court subject matter jurisdiction to conduct such contempt proceedings. Therefore, asserts Apotex, the contempt proceeding was a nullity. In the alternative, Apotex argues that contempt proceedings were improper in any event, because the infringement inquiry was amenable only to trial under the Federal

Rules of Civil Procedure. We address each argument in turn below.

We review subject matter jurisdiction de novo. *Kunkel v. Topmaster Int'l, Inc.*, 906 F.2d 693, 695 (Fed.Cir.1990). Apotex argues that a contempt proceeding is unlawful in the context of a Hatch-Waxman suit because such a lawsuit is filed before the accused infringer has engaged in any "classically infringing" activity—i.e., making, using, selling or offering to sell, or importing into the U.S. the patented drug. Apotex argues that, because it did not engage in any of these activities but merely filed a second ANDA, it has at most committed an act of "artificial infringement" and therefore cannot be called to answer for any alleged violation of the first injunction in a contempt proceeding.

Apotex's characterization of "classically infringing" activity is legally meaningless. As we have held numerous times, the filing of a paragraph IV certification is itself an act of infringement if the purpose of the ANDA submission is to obtain the FDA's approval to engage in the commercial manufacture, use, or sale of a patented drug before expiration of the drug patent. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1245 (Fed.Cir.2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1567 (Fed.Cir.1997); *see also* 35 U.S.C. § 271(e)(2)(A). While the Supreme Court has characterized infringement as defined in the Hatch-Waxman Act as "highly artificial," *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990), by statutory command it is

infringement nonetheless. Apotex has failed to provide any authority, be it statute, case law, or legislative history of the Hatch-Waxman Act, suggesting that suits commenced under the provisions of the Act are to be treated any differently than patent infringement suits under 35 U.S.C. § 271(a). Indeed, we have previously held that the district court's infringement analysis in a Hatch-Waxman suit is no different than that in any other patent infringement suit. *Glaxo*, 110 F.3d at 1569.

Further, Apotex errs by looking only to the district court's authority under the Hatch-Waxman Act when well-settled principles of equity govern injunctions in patent disputes just as in disputes in other areas of law. *See eBay Inc. v. MercExchange, L.L.C.*, __ U.S. __, 126 S.Ct. 1837, 1841, 164 L.Ed.2d 641 (2006). The power of a district court to enforce its injunction through contempt proceedings is no different, and section 355(j)(5)(B)(iii) of Title 21 does not counsel otherwise. The statute is simply silent regarding a district court's contempt authority. Because we assume Congress's familiarity with general principles of law when enacting a statute, Congress must have intended for the courts to maintain their inherent authority to enforce their own injunctions under the well-established principles of equity. *See Raney v. Federal Bureau of Prisons*, 222 F.3d 927, 932 (Fed.Cir.2000) ("Congress is presumed to enact legislation with knowledge of the law and a newly-enacted statute is presumed to be harmonious with existing law and judicial concepts.") (*citing Cannon v. Univ. of Chi.*, 441 U.S. 677, 696-98, 99 S.Ct. 1946, 60

L.Ed.2d 560 (1979)). Therefore, the district court clearly had subject matter jurisdiction.

Apotex asserts that the district court abused its discretion in proceeding via a contempt proceeding because any determination of infringement in this case would require "scientific testing, expert opinions, and a host of credibility determinations" that would preclude a contempt proceeding. Appellant Br. at 45. It is true that we have counseled against contempt proceedings of a summary nature where " 'expert and other testimony subject to cross-examination would be helpful or necessary.' " *Arbek Mfg., Inc. v. Moazzam*, 55 F.3d 1567, 1570 (Fed.Cir.1995) (*quoting KSM Fastening Sys., Inc. v. H.A. Jones Co., Inc.*, 776 F.2d 1522, 1531 (Fed.Cir.1985)). However, we have said so in the context of a former infringer "who has made a good-faith effort to modify a previously adjudged or admitted infringing device to remain in the marketplace." *Arbek Mfg.*, 55 F.3d at 1570. The district court found that "Apotex's choice of Nu-Pharm to file the ANDA was a subterfuge intended to give Apotex a crack at another district judge" who might find that Nu-Pharm ANDA drug noninfringing. *Abbott V*, 455 F.Supp.2d at 835. We do not disturb that finding, and conclude that the district court did not abuse its discretion in electing to try issues relating to the Nu-Pharm ANDA in a contempt proceeding. *See also Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 154 F.3d 1345, 1349 (Fed.Cir.1998) (need for expert testimony not dispositive).

Notwithstanding the above, we have held that before entering a judgment of contempt of an injunction in a patent infringement case, a district court must address two separate questions. First, the district court must address whether a contempt hearing is an appropriate forum for adjudging whether an allegedly redesigned product is infringing. *KSM Fastening Sys.*, 776 F.2d at 1532; *Additive Controls*, 154 F.3d at 1349-50. In doing so, the district court must compare the accused product with the original infringing product. If there is "more than a colorable difference" between the accused product and the adjudged infringing product such that "substantial open issues with respect to infringement to be tried" exist, contempt proceedings are not appropriate. *KSM Fastening*, 776 F.2d at 1532.[3]

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3. The dissent correctly notes that both the Supreme Court and this court have evaluated, as a threshold question in deciding whether summary contempt proceedings are proper, whether there is "fair ground for doubt as to the wrongfulness of the defendant's conduct." Dissent at 1384 (quoting *Cal. Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609, 618, 5 S.Ct. 618, 28 L.Ed. 1106 (1885)). In patent infringement cases, this inquiry has been restated as whether there is a colorable difference between the accused and adjudged devices. *KSM Fastening*, 776 F.2d at 1530. More generally, this court has stated that "[t]he presence of [ ] disputed issues creates a fair ground for doubt that the decree has been violated." *Id.* at 1532. Requiring disputed issues to be tried through full litigation rather than summary proceedings eliminates due process concerns for the defendant accused of violating an injunction. *Id.*

(Cont'd)

We review the district court's decision to entertain a contempt proceeding for an abuse of discretion, applying Federal Circuit law. *Id.* "An abuse of discretion may be established under Federal Circuit law by showing that the court made a clear error of judgment in weighing the relevant factors or exercised its discretion based on an error of law or clearly erroneous fact finding."

(Cont'd)

In applying the "fair ground of doubt" test in this case, however, the dissent does not identify any *doubt* (e.g., based on the facts or issues of the case) that would require full litigation rather than summary proceedings. The dissent does not identify any colorable difference between the adjudged and accused products, and thus seems to agree that there was no "fair ground of doubt" as to the lower court's determination of infringement. Instead, the dissent states in a rather conclusory fashion that there was a "fair ground of doubt" because we hold that the injunction did not preclude the filing of the Nu-Pharm ANDA. Dissent at 1384. But the dissent does not indicate what was *doubtful* about this determination. Either the ANDA falls within the scope of the plain language of the injunction, or it does not. Quite tellingly, the dissent would have us remand for the district to decide the infringement question in a new proceeding (although there is no "fair ground of doubt" regarding infringement), Dissent at 1385, but does not suggest that the new proceeding should also determine whether filing an ANDA violated the injunction. Since neither infringement nor the inapplicability of the injunction to the accused conduct was doubtful, summary determination before the district court was appropriate. A different rule would require a defendant to participate in full litigation, even though he could be absolved summarily of contempt liability when, as here, there is no doubt about the issue at hand. Such a rule would serve neither defendant's due process interests nor judicial economy.

Lab. Corp. of Am. Holdings v. Chiron Corp., 384 F.3d 1326, 1331 (Fed.Cir.2004) (quoting *Int'l Rectifier Corp. v. Samsung Elecs. Co., Ltd.*, 361 F.3d 1355, 1359 (Fed.Cir.2004)).

Second, if contempt proceedings are appropriate, the district court must address whether the accused product infringes the claims of the asserted patent. *Additive Controls*, 154 F.3d at 1349. To show infringement, the patentee "must prove by clear and convincing evidence that 'the modified device falls within the admitted or adjudicated scope of the claims.' " *Arbek Mfg.*, 55 F.3d at 1569 (*quoting KSM Fastening*, 776 F.2d at 1530).

Here, we hold that the district court did not abuse its discretion in holding contempt proceedings. Judge Posner carefully reviewed the evidence presented by the parties and assessed the credibility of the witnesses. Clear and convincing evidence, including Apotex's own evidence, supports his finding that there is no more than a colorable difference, if any, between the Apotex ANDA drug and the Nu-Pharm ANDA drug. Specifically, Apotex's own expert, Dr. Stephens, testified that when he tested and compared the Apotex ANDA drug with the Nu-Pharm ANDA drug, they were identical. Where, as here, a party files a second ANDA to a drug having no more than a colorable difference from the first, the district court is well within its discretion to entertain contempt proceedings.

Further, the district court did not clearly err in finding that Abbott proved by clear and convincing

evidence that the Nu-Pharm ANDA drug would infringe the claims of the Abbott patents. Even though the district court already had strong documentary evidence suggesting that there was no difference between the adjudicated infringing drug and the accused drug, the district court relied on fresh evidence presented by Abbott's expert, Dr. Atwood, showing that the Nu-Pharm ANDA drug is an oligomer. The evidence was based on results obtained by Dr. Atwood from freezing-point depression, vapor phase osmometry, and FAB mass spectrometry tests. The district court also found that Abbott's expert was more credible than Apotex's experts. Considering all the evidence, the district court did not clearly err in holding that the NuPharm ANDA drug would infringe the claims of the Abbott patents.

From the above, it follows that Judge Posner acted entirely within his discretionary authority to issue an order expanding the original injunction. *See Conoco, Inc. v. Energy & Envtl. Int'l, L.C.,* 460 F.3d 1349, 1357 (Fed.Cir.2006) ("We review a district court's decision to extend injunctive relief for an abuse of discretion.") (*citing Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 404 (Fed.Cir.1989)). We note that the original injunction clearly prohibited the FDA from approving the Apotex application and "any other application concerning defendants' generic divalproex sodium which the Court has found to be infringing." The language of the injunction was upheld in *Apotex IV* and cannot be challenged now. Because the Nu-Pharm ANDA drug would infringe the claims of the Abbott patents, the district court did not abuse its discretion in extending

the injunction to prohibit the FDA from approving the Nu-Pharm ANDA. Therefore, we decline to vacate the revised injunction as Apotex requests.

Finally, Apotex complains that it did not have adequate time in which to obtain formal comparative testing results. We note, however, that Apotex failed to request a continuance from the district court. Further, rather than follow the district court's order to explain why more time was necessary, Apotex simply filed further declarations. Apotex cannot complain now and we disregard these arguments.

C

We now turn to the finding of contempt. We review the district court's finding of contempt for an abuse of discretion, again applying Federal Circuit law. *KSM Fastening Sys.*, 776 F.2d at 1532. There must be clear and convincing evidence of patent infringement to support a district court's finding of contempt. *Id.* As with any other legal instrument, interpretation of the terms of an injunction is a question of law we review de novo. *See Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 951 (Fed.Cir.1997) ("[J]udicial rulings, like statutes, are official legal instruments ... reviewed de novo on appeal."); *see also Schering Corp. v. Ill. Antibiotics Co.*, 62 F.3d 903, 908 (7th Cir.1995) ("The interpretation of documents, including judicial decrees, is, when no factual disputes intrude and no collation of possibly inconsistent documents is required, traditionally an issue of law. . . .").

We hold that the district court made an error of law in interpreting its original injunction to preclude the conduct of which Abbott complains, namely the filing of the Nu-Pharm ANDA, and thereby abused its discretion in holding Apotex in contempt. As noted above, Judge Posner interpreted the injunction issued in *Abbott III* as prohibiting Apotex from manufacturing any generic divalproex sodium the court found to be infringing. *Abbott V*, 455 F.Supp.2d at 835. While we agree that Apotex could not manufacture generic divalproex sodium in the United States, there is no evidence here that Apotex actually did so. Rather, it is undisputed that Apotex's actions in attempting to design around the Abbott patent claims occurred outside the United States. Since Apotex did not make, use, sell, offer to sell in the U.S. or import into the U.S. generic divalproex sodium, it did not violate the injunction. *See Int'l Rectifier Corp.*, 361 F.3d at 1360 (holding permanent injunction not violated because accused infringer's acts did not take place within the United States).

Further, while we agree that Apotex's filing of the Nu-Pharm ANDA with a paragraph IV certification was an act of infringement under 35 U.S.C. § 271(e) since Apotex's purpose in doing so was to obtain the FDA's approval to market generic divalproex sodium in the U.S. before expiration of the Abbott patents, we cannot agree that Apotex's actions actually violated the original injunction. In this regard, the district court impermissibly interpreted the original injunction as prohibiting acts beyond its plain terms in violation of Fed.R.Civ.P. 65(d). Rule 65(d) provides that "[e]very

order granting an injunction . . . shall be specific in terms [and] shall describe in reasonable detail, and not by reference to the complaint or other document, the act or acts sought to be restrained." The Supreme Court has made clear that Rule 65(d)

> was designed to prevent uncertainty and confusion on the part of those faced with injunctive orders, and to avoid the possible founding of a contempt citation on a decree too vague to be understood. [B]asic fairness requires that those enjoined receive explicit notice of precisely what conduct is outlawed.

Schmidt v. Lessard, 414 U.S. 473, 476, 94 S.Ct. 713, 38 L.Ed.2d 661 (1974) (citations omitted). The Court has also said: "When [the judicial contempt power] is founded upon a decree too vague to be understood, it can be a deadly one. . . . [T]hose who must obey [injunctions must] know what the court intends to require and what it means to forbid." *Int'l Longshoremen's Ass'n, Local 1291 v. Phila. Marine Trade Ass'n*, 389 U.S. 64, 76, 88 S.Ct. 201, 19 L.Ed.2d 236 (1967). These concerns have led courts to construe injunctions narrowly where, as here, they failed to give adequate notice that particular conduct was enjoined. *See, e.g., Ford v. Kammerer*, 450 F.2d 279, 280 (3d Cir.1971) ("[Injunctions] are binding only to the extent they contain sufficient description of the prohibited or mandated acts. . . . [A]mbiguities and omissions in orders redound to the benefit of the person charged with contempt."); 11A Wright & Miller, Federal Practice &

Procedure § 2955 ("Since . . . only those acts specified by the order will be treated as within its scope and . . . no conduct or action will be prohibited by implication, all omissions or ambiguities . . . will be resolved in favor of [the enjoined party].").

By its plain language, the injunction issued in *Abbott III* only (1) enjoined Apotex from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing within the United States and importing such product into the United States until expiration of the Abbott patents, and (2) prohibited the FDA from approving the Apotex ANDA as well as any other ANDA application filed by Apotex directed to generic divalproex sodium which the Court has found to be infringing until expiration of the Abbott patents. In other words, while contemplating the filing of new and/or amended ANDAs, the injunction only provided the FDA with the necessary "explicit notice" that it was prohibited from approving the Apotex ANDA or any other ANDA concerning Apotex's generic divalproex sodium which a court found to be infringing prior to expiration of the Abbott patents. The injunction contains no "explicit notice" to Apotex that the filing of a new ANDA, by itself or a straw party, was forbidden. Therefore, Apotex is foreclosed only from the conduct specifically prohibited, i.e., making, using, selling, offering for sale in the U.S. or importing into the U.S. infringing generic divalproex sodium.

We agree with Abbott that it is settled law that courts possess broad equitable powers to enforce their own

decrees. *See e.g., KSM Fastening Sys.*, 776 F.2d 1522. However, we cannot and do not purport to rewrite the original injunction because Apotex had no explicit notice that it was enjoined from filing a second ANDA. Accordingly, the district court's judgment of contempt is

REVERSED.

DYK, Circuit Judge, concurring-in-part and dissenting-in-part.

I agree with the majority's conclusion that the original injunction did not bar TorPharm, Inc., Apotex, Inc., and Apotex Corporation (collectively, "Apotex") from filing a new ANDA, and that the district court could not properly find Apotex in contempt. Maj. Op. at 1381-83. In my view, since there was a "fair ground of doubt" from the outset as to whether the injunction applied, it necessarily follows that contempt proceedings were inappropriate. However, the majority reaches the puzzling conclusion that proceedings in contempt were nonetheless permissible, and that the district court could properly determine in those proceedings that the Nu-Pharm ANDA product would infringe the relevant patent claims and extend the injunction as a remedy for this violation. I respectfully dissent from that aspect of the majority decision.

The Supreme Court has said that "[p]rocess of contempt is a severe remedy, and should not be resorted to where there is fair ground of doubt as to the wrongfulness of the defendant's conduct." *Cal. Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609, 618, 5 S.Ct. 618, 28 L.Ed. 1106 (1885). Thus, we have similarly established that "[i]f there is a fair ground of doubt as to the wrongfulness of the defendant's actions said to be in contempt, the District Court should not entertain the civil contempt proceeding or find contempt." *Preemption Devices, Inc. v. Minn. Mining & Mfg. Co.*, 803 F.2d 1170, 1173 (Fed.Cir.1986); *see also KSM Fastening Sys., Inc.*

v. H.A. Jones Co., 776 F.2d 1522, 1525 (Fed.Cir.1985). For example, in *MAC Corp. of Am. v. Williams Patent Crusher & Pulverizer Co.*, 767 F.2d 882 (Fed.Cir.1985), we affirmed the district court's refusal to proceed in contempt where there was a "fair ground for doubt" based on differences between the accused and enjoined products. *Id.* at 886. For that reason, "it would not be in the interest of justice to determine the merits of th[e] dispute in summary proceedings for contempt," and instead the appropriate procedure was to "give MAC its full day in court when [the district court] hears and determines Williams' action for declaratory judgment of non-infringement and MAC's counterclaim for infringement." *Id.*

The act alleged to constitute contempt here was the filing of the Nu-Pharm ANDA. Given the majority's conclusion that the "original injunction ... [did not] preclude the conduct of which Abbott complains, namely the filing of the Nu-Pharm ANDA," there was clearly a "fair ground of doubt" as to whether Apotex's conduct was wrongful under the injunction. Maj. Op. at 1382. Summary contempt proceedings were therefore inappropriate. The majority reaches a different conclusion by holding that contempt proceedings are appropriate as long as there is no more than a "colorable difference" between the accused and enjoined products. Maj. Op. at 1380-81. The majority relies on our cases holding that "proceedings by way of contempt should not go forward if there is more than a 'colorable difference' in the accused and adjudged devices." *KSM Fastening*, 776 F.2d at 1530. Of course, this statement in

KSM Fastening does not make the contrary proposition true: contempt proceedings are not necessarily appropriate just because there are not colorable differences between an accused and an enjoined device. In the colorable differences cases, unlike the present one, the alleged contempt consisted of producing the product covered by the injunction. Under these circumstances, the "colorable difference" test is just a specific application of the more general "fair ground of doubt" test. *See id.* at 1525. By focusing only on the narrower, inapplicable "colorable differences" test, the majority concludes that contempt proceedings were appropriate in this case. In my view, this is contrary to Supreme Court decisions and our own precedent.

If I am correct that contempt proceedings were improper, it necessarily follows that any decisions made in the course of those proceedings must be vacated. It is well established that determinations reached in the course of a proceeding can be given preclusive effect "only if the court has authority to adjudicate the type of controversy involved in the action." Restatement (Second) of Judgments § 11 (1982). Denying effect to the district court's infringement determination is particularly appropriate in this case, because the infringement determination was directly affected by the nature of the proceedings. The district court declined to consider additional evidence submitted by the appellant specifically because of the summary nature of the contempt proceeding. *See Abbott Labs. v. Apotex, Inc.*, 455 F.Supp.2d 831, 837 (N.D.Ill.2006). Thus, the finding of infringement should be vacated so that the issue can

be considered anew by Judge Pallmeyer in the pending infringement suit. *See MAC Corp.*, 767 F.2d at 886 (noting that when a "fair ground of doubt" existed the merits of the dispute should not be resolved in summary contempt proceedings but instead through a full infringement trial).

Similarly, it follows that the remedies imposed based on the finding of infringement must be vacated. In this case, the contempt remedy imposed by the district court was the extension of the injunction based on a finding of infringement. In fact, the district court explicitly noted that Abbott requested "a determination that Apotex ha[d] violated the injunction" and a resulting "extension (modification) of the injunction" rather than "monetary sanctions or imprisonment." *See Abbott Labs.*, 455 F.Supp.2d at 833. At the end of its opinion, the district court held that "[t]he injunction ha[d] been violated" and noted that future violations of the injunction would result in "heavy [monetary] sanctions" but that "[f]or the present ... it will suffice to extend the injunction to embrace the Nu-Pharm ANDA." *Id.* at 840. The extension of the injunction should be vacated, given the inappropriateness of contempt proceedings.[1]

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1. While a district court certainly has equitable powers to modify its own orders and injunctions in some circumstances, *see United States v. United Shoe Machinery Corp.*, 391 U.S. 244, 249, 88 S.Ct. 1496, 20 L.Ed.2d 562 (1968), the proceedings in this case were not instituted for that purpose, but rather were summary contempt proceedings.

APPENDIX B — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED OCTOBER 6, 2006

UNITED STATES DISTRICT COURT
N.D. ILLINOIS
EASTERN DIVISION

No. 97 C 7515.

Oct. 6, 2006.

ABBOTT LABORATORIES,

Plaintiff,

v.

APOTEX, INC. and Apotex Corporation,

Defendants.

OPINION

RICHARD A. POSNER, Circuit Judge, sitting by designation.

In 1997, Abbott Laboratories filed this suit for patent infringement against TorPharm, Inc., a manufacturer of generic pharmaceutical drugs, and affiliates of TorPharm, notably Apotex, Inc., its parent. (TorPharm has since been absorbed into its parent, so I have

dropped it from the caption and throughout this opinion refer to TorPharm as Apotex.) The district judge initially assigned to the case granted summary judgment in favor of Abbott on both validity and infringement. 156 F.Supp.2d 738 (N.D.Ill.2001). The Federal Circuit affirmed the ruling on validity but remanded for a trial on infringement. 300 F.3d 1367 (Fed.Cir.2002). I was designated to conduct the trial (28 U.S.C. § 291(b))-a bench trial, because Abbott was seeking only equitable relief. Indeed, it could not seek damages, because Apotex had not yet begun to market its generic substitute for Abbott's product. At the conclusion of the trial, I held that Apotex had infringed, *Abbott Laboratories v. TorPharm, Inc.*, 309 F.Supp.2d 1043 (N.D.Ill.2004), and after considering further submissions from the parties, dealing with relief, I issued an injunction, No. 97 C 7515 (N.D.Ill. Mar. 31, 2004), which the Federal Circuit affirmed. 122 Fed.Appx. 511 (Fed.Cir.2005). The case is back before me on a motion by Abbott to rule that Apotex has violated the injunction. When an equity case ends in a permanent injunction, the trial court, with or without an explicit reservation of jurisdiction, retains jurisdiction to enforce the injunction, as by contempt proceedings. *McCall-Bey v. Franzen*, 777 F.2d 1178, 1183 (7th Cir.1985); see also *Riverdale Cotton Mills v. Alabama & Georgia Mfg. Co.*, 198 U.S. 188, 195, 25 S.Ct. 629, 49 L.Ed. 1008 (1905). Necessarily, therefore, the judge who issues an injunction has the authority to interpret it if a dispute arises over its scope, *In re China Peak Resort*, 847 F.2d 570, 571-72 (9th Cir.1988), vacated on other grounds under the name *California State Bd. of Equalization v. Sierra Summit, Inc.*, 490 U.S. 844, 109

S.Ct. 2228, 104 L.Ed.2d 910 (1989); *Wilson v. Alexander*, 276 F. 875, 881 (5th Cir.1921)-and indeed is in a better position than anyone else to do so. *Schering Corp. v. Illinois Antibiotics Co.*, 62 F.3d 903, 908 (7th Cir.1995); *In re Chicago, Rock Island & Pacific R.R.*, 860 F.2d 267, 272 (7th Cir.1988). But the issue here is not the meaning of the injunction; the meaning is clear; the issue is whether the injunction has been violated. If it has been, even if in good faith, that is a civil contempt, *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191, 69 S.Ct. 497, 93 L.Ed. 599 (1949); *Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc.*, 154 F.3d 1345, 1353 (Fed.Cir.1998), and I can so rule without imposing monetary sanctions or imprisonment. Abbott is not requesting such sanctions at this time; it is content with a determination that Apotex has violated the injunction and with an extension (modification) of the injunction to eliminate any possible ambiguity about its reaching the new Apotex product.

A finding of contempt requires proof by clear and convincing evidence, e.g., *Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc., supra*, 154 F.3d at 1355-56, *Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co.*, 803 F.2d 1170, 1172-73 (Fed.Cir.1986), a rule that is appropriate because of the summary character of contempt proceedings. See, e.g., *KSM Fastening Systems, Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1524 (Fed.Cir.1985). That is the standard that will guide my inquiry.

Appendix B

The patent (actually two patents, but I will pretend they're one because they don't differ in any respect material to this opinion) is on a chemical called divalproex sodium, which Abbott sells under the trade name Depakote for the treatment of epilepsy and other ailments. The chemical is a complex of two molecules, one of sodium valproate and one of valproic acid. Although either sodium valproate or valproic acid would have all the desired therapeutic properties of the drug, combining them produces a crystalline solid that is easier to manufacture into pills than either of its constituents.

For reasons never adequately explained, Abbott's patent is limited to divalproex sodium in the form of an oligomer consisting of about 4 to 6 units of divalproex sodium. Just as the sodium valproate and valproic acid molecules combine to form the divalproex sodium complex, so two or more of these complexes might join together to form a larger structure, such as a crystal, which might consist of millions or billions of identical units, whether atoms, molecules, or looser complexes. A polymer is an assemblage of a large number of smaller molecules. At the opposite extreme is a monomer, implying no discernible linkage with neighboring units of the same chemical. An oligomer, as the name implies (cf.oligopoly), is an assemblage of several rather than, as in the case of a polymer, many identical units.

In the infringement trial, Abbott presented compelling evidence that Apotex's product is indeed an oligomer, and therefore infringes; hence the injunction. Of course there would be no infringement if, as Apotex

argued, Abbott's product was not an oligomer; for then Abbott's patent would be invalid. In the first round of this litigation, however, the Federal Circuit held unequivocally that Abbott's divalproex sodium is indeed an oligomer. 300 F.3d at 1372, 1378. That was the law of the case when I tried the infringement claim; and it might seem that now, by virtue of the doctrine of collateral estoppel, it precludes Apotex from relitigating the issue, since the finding undergirds the final judgment enjoining it. But collateral estoppel precludes relitigation of an issue in a subsequent case, and the present proceeding, initiated by a motion filed in an existing case (Abbott's infringement suit against TorPharm and Apotex), is not a subsequent case, and so it is the law of the case doctrine, rather than collateral estoppel, that limits relitigation. *KSM Fastening Systems, Inc. v. H.A. Jones Co., supra*, 776 F.2d at 1524, 1529.

The Federal Circuit in the first round of appeals made findings concerning Apotex's product that strongly suggested that it was identical to Abbott's. Nevertheless, it was at least conceivable that differences in the production process (Abbott uses a solvent in manufacturing divalproex sodium while Apotex just mixed the sodium valproate and the valproic acid and heated the mixture to produce divalproex sodium) might somehow prevent the oligomeric structure from forming in Apotex's product. However, evidence at the trial, at which Abbott's principal witness—an eminent supramolecular chemist named Jerry Atwood—reported the results of five different types of test that he had conducted on a batch of Apotex's product left no doubt

in my mind that the product was indeed an oligomer; that despite the difference in process, it was identical to the patented product. (Apotex had conducted no tests.) There is no need to summarize the evidence or my analysis of it; the reader can consult my previous opinion. 309 F.Supp.2d at 1047-54.

One further point about the trial is worth nothing, however. Apotex wanted to prove, mainly through testimony by Dr. Bernard Sherman, Apotex's principal, that Atwood's tests, and the earlier tests that had convinced the Patent Office that Abbott's product was an oligomer, were fatally flawed, that it was not an oligomer and therefore the patent (limited, as I said, to a divalproex sodium oligomer) was invalid. Sherman, I ruled, was no more qualified to testify about Abbott's tests than about Apotex's. He is a chemical engineer, not an analytical chemist. I noted also that the issue he wanted to reargue, concerning the chemical structure of Abbott's product (was it or was it not an oligomer?) was not only beyond his professional competence, but was made irrelevant by the Federal Circuit's decision upholding the validity of Abbott's patent.

In March 2005, a year after I issued the injunction, another Canadian company, Nu-Pharm, Inc., filed with the Food and Drug Administration an Abbreviated New Drug Application (ANDA) for a divalproex sodium product. Nu-Pharm is a tiny (six employees) company formerly owned by Apotex. It markets drugs for Apotex in Canada. It has never marketed a drug in the United States, and it does not develop or test drugs. The product

for which Nu-Pharm filed the ANDA had been developed by Apotex, is owned by it, and, as Sherman has testified, we [Apotex] will get our profit out of it, anyway.

It is obvious, and I find, that Apotex's choice of Nu-Pharm to file the ANDA was a subterfuge intended to give Apotex a crack at another district judge, who might, in an infringement suit by Abbott, conclude that it was a different, and noninfringing, product from the one I had enjoined. Abbott did sue Nu-Pharm for infringement, because it was unaware that Nu-Pharm was merely a stalking horse for Apotex. Had Abbott known, it would not have bothered with the other suit *Abbott Laboratories v. Nu-Pharm, Inc.*, 2005 WL 1768541 (N.D.Ill. filed June 24, 2005), which under the local rules was quite likely to end up before another judge; see N.D. Ill. Local Rule 40.3(b); it would have moved, as it now has, for relief in the original proceeding. (The judge in the Nu-Pharm suit has stayed proceedings pending my ruling on Abbott's motion.) I infer that Sherman hoped to get a favorable decision or ruling in that case before Abbott woke up, penetrated the veil, and sought to enforce its injunction against the new ANDA.

Under Federal Circuit case law, I may determine infringement in this contempt proceeding only if a summary proceeding is adequate for deciding whether the redesigned product (the subject of the Nu-Pharm ANDA) infringes the patent, and thus violates the injunction; otherwise I must remit the issue of infringement to a separate suit charging infringement by the new product (in this case, it would be Abbott's

suit against Nu-Pharm and Apotex, pending before the other judge.) Specifically, I must do that if I find that there is more than a "colorable difference" in the accused and adjudged devices, which is to say if there are substantial open issues with respect to infringement to be tried, since the presence of such disputed issues creates a fair ground for doubt that the decree has been violated. *KSM Fastening Systems, Inc. v. H.A. Jones Co., supra*, 776 F.2d at 1530, 1532; see also *California Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609, 614, 5 S.Ct. 618, 28 L.Ed. 1106 (1885); *Conoco, Inc. v. Energy & Environmental Int'l, L.C.*, 460 F.3d 1349, 1365 (Fed.Cir. Aug. 17, 2006), 2006 U.S.App. LEXIS 21036, at *39; *Stryker Corp. v. Davol, Inc.*, 234 F.3d 1252, 1260 (Fed.Cir.2000).

The injunction extends to any generic divalproex sodium manufactured by Apotex that had been found to be infringing. At the evidentiary hearing on Abbott's motion to determine that Apotex through its tool Nu-Pharm was violating the injunction, which I conducted on August 30, Atwood testified that he had performed on the new product three of the five tests that he'd performed on the old one (freezing-point depression, vapor phase osmometry, and FAB mass spectrometry—the others are melting point and solubility) on the new one and that a consulting firm, SSCI, Inc., had conducted a fourth, a melting-point analysis, plus four tests that had not been done in the original litigation—powder X-ray diffraction, solid state C nuclear magnetic resonance spectroscopy, infrared spectroscopy, and elemental analysis. He testified that all the tests (besides

his own tests, he had reviewed the test data and results of the tests conducted by SSCI.) had revealed, within the margins of error accepted by the chemistry profession, that Nu-Pharm's product was chemically identical to both Abbott's product and the original Apotex product, including in structure (i.e., oligomeric). True, he testified only that the tests that *he* had performed were within the accepted margins of error, but his expert report stated that all of the experiments conducted or commissioned by SSCI ... were scientifically sound, based on accepted scientific procedures, and produced reliable results, implying that their results, too, were within the accepted margins of error, for otherwise the results would not have been reliable.

Apotex responded that it had altered the process of making its product by raising the heat level, but it presented no evidence that the alteration (or a different process, called spray dry, that it also used to make the new divalproex sodium product) necessarily or even probably would alter the oligomeric structure. From admissions in the deposition testimony of Dr. Sherman, it is plain, and I find, that he altered the manufacturing process not on the basis of any scientific evidence that it would produce a different product (for different processes can produce the identical product) but because he was unshaken in his belief (now rejected by two courts-this court and the Federal Circuit) that divalproex sodium is never an oligomer, and he wanted additional shots at persuading a court. Thus, in changing the process, Sherman was hoping to come up with a product

that would be found by a court to be noninfringing, not necessarily a product that *was* noninfringing. He admitted not only that testing might or might not show that the Nu-Pharm product was different from Abbott's product and from Apotex's original product, but also that the Nu-Pharm product might be even *more* likely to infringe Abbott's product than his original product was. This is stubbornness carried to the point of contumacy.

Apotex did, however, present the testimony of a reputable chemist, Michael Hursthouse, who conducted a test that had not been conducted in the original proceeding—single crystal X-ray diffraction analysis—which showed, he testified, that the new product was probably a polymer rather than an oligomer. Another chemist who testified for Apotex, Peter Stephens, modified Hursthouse's model of the new product to make it consistent with data that Stephens had obtained in a second test—powder X-ray diffraction analysis—a test also performed by SSCI, on behalf of Abbott, on the new Apotex, old Apotex, and Abbott samples. Stephens testified that his analysis also indicated that the new Apotex product was probably a polymer.But the analyses by Apotex's expert witnesses did not indicate that the new product was different from the old one, because they did not conduct their tests on that product. For all that appears, the test results would have been identical—with one exception: Stephens did run his powder X-ray diffraction test on the Abbott sample, and, consistent with SSCI's results from this test, his preliminary results indicated that it was identical to the new Apotex sample. That of course was a finding helpful to Abbott.

Appendix B

A third expert witness for Apotex (Michael Cima) testified that changing the process for making divalproex sodium *could* change the chemical structure of the resulting product, but that to determine whether it had changed it would require testing that he had not done.

At the conclusion of the evidentiary hearing, Apotex's counsel asked for more time before I ruled, in order to enable Apotex's experts to conduct their tests on Apotex's original product. I asked the parties to submit posthearing briefs that would include discussion of whether Apotex should be given additional time to present evidence. Although I asked for a brief, not for evidentiary submissions, Apotex has included with its brief affidavits reporting new test results and new analyses of the tests conducted previously. I did not authorize such submissions—only briefs on whether to authorize them-and they are hereby stricken. I have, however, considered three affidavits submitted after the August 30 hearing that presented testimony that otherwise could have been presented live at the hearing—an affidavit from Atwood, concerning his critique of Hursthouse' experiments, that I specifically requested from Abbott at the hearing, plus Hursthouse's response to the new affidavit, plus a further affidavit from Atwood replying to the response.

Upon consideration of the posthearing briefs, I have decided that to permit Apotex to extend this proceeding with further evidentiary hearings would simply reward its contumacy. The hearing that I held on August 30 revealed, consistent with Dr. Sherman's deposition, that

Apotex had conducted no tests on the Nu-Pharm product before Nu-Pharm at Apotex's behest filed the ANDA in which it certified that the product was noninfringing.

A person or firm that has been enjoined has a duty to make a good-faith effort to comply with the injunction. For the principle, see *Stotler & Co. v. Able*, 870 F.2d 1158, 1163 (7th Cir.1989); *American Fletcher Mortgage Co. v. Bass*, 688 F.2d 513, 517 (7th Cir.1982), and *Peppers v. Barry*, 873 F.2d 967, 969 (6th Cir.1989), and for its application to patent injunctions *Stryker Corp. v. Davol, Inc.* 75 F.Supp.2d 741, 743 (W.D.Mich.1999), affirmed, 234 F.3d 1252 (Fed.Cir.2000). So it behooved Apotex to test its new divalproex sodium product to make sure it wasn't an oligomer. It did not do this. It changed the process, but without obtaining a scientific opinion that this would change the structure, let alone testing the new product and Abbott's product to see whether the new product infringed. Even after being challenged by Abbott's motion it ran no tests to determine whether the new product was in fact different from the old one. One of the chemists who testified for Apotex at the hearing (Stephens) performed his test on the Abbott product, and eyeballing the result (but going no further) thought it looked the same. The fact that he did not complete his comparison of the Abbott product with the new Apotex product raises an inference that he feared what the result would be.

Because there is no credible evidence that the new Apotex product is different from the old, the enjoined, one and much evidence to the contrary, the threshold

test for contempt of a patent injunction has been met: there is no more than a colorable difference between the new product and the infringing old product. (By colorable is meant slight. Here, there is no difference at all.) But the Federal Circuit, wishing to encourage pharmaceutical companies to design around patented products, has ruled that a finding of no more than a colorable difference merely establishes that it is proper to determine infringement in the contempt proceeding rather than having to confide the issue to determination in a new infringement suit. *Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc., supra,* 154 F.3d at 1349-50; *KSM Fastening Systems, Inc. v. H.A. Jones Co., supra,* 776 F.2d at 1532.

It might seem that if the old product infringed and the new product is identical to the old product, it must infringe as well. But that is not correct. A product is infringing only if it infringes the claims in the patent, and the patented product might not have embodied the claims. Suppose Abbott's product hadn't been an oligomer; then even if Apotex's new product were identical to Abbott's, it would not infringe the patent, because the patent is limited to divalproex sodium in oligomer form. That is why The Federal Circuit considers it error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process and holds that the only proper comparison is with the claims of the patent. *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed.Cir.1994); see also *Spectrum Int'l, Inc.*

v. Sterilite Corp., 164 F.3d 1372, 1381 (Fed.Cir.1998); *KSM Fastening Systems, Inc. v. H.A. Jones Co., supra*, 776 F.2d at 1530. But as I noted earlier, Abbott's product has been found to be an oligomer, and thus to be within the patent claims. So if Apotex's new product is identical to Abbott's-and the clear and convincing evidence demonstrates that it is-it must be an oligomer too.

In any event there is fresh, independent, and compelling evidence that Apotex's new product is an oligomer—the evidence that Professor Atwood presented at the August 30 hearing. From the results of the freezing-point depression, vapor phase osmometry, and FAB mass spectrometry tests that Dr. Atwood performed in this phase of the case, he concluded that the Nu-Pharm product was an oligomer. The experiments were part of the battery of experiments that convinced me in the first case that Apotex's (old) product was an oligomer. Atwood obtained the same results when he ran these tests on the Nu-Pharm samples as he had obtained when he had run the tests on the Abbott and (old) Apotex samples, and the results were further supported by his review of the battery of tests performed by the consulting firm. The result of the melting-point test, performed by the firm, is especially instructive because, as I noted in the original case, melting point is strongly probative of oligomeric structure. The melting point of the Nu-Pharm samples was within the 98-100°C range set forth in the patent.

Atwood was, moreover, more credible than Apotex's experts. Stephens, for example, omitted from his expert

report his preliminary conclusion that the Abbott and Nu-Pharm products were identical (the conclusion was brought out on cross-examination), and Cima made no attempt to explore or explain the chemical structure of any divalproex sodium product. There are further problems with the evidence given by Stephens, and problems with Hursthouse's evidence as well. I mentioned their failure (except for one test by Stephens—the result of which supported Abbott's case!) to run their tests on the Abbott and (old) Apotex products. In addition, Hursthouse's model did not agree well with the data, as judged by R value, a measure of the discrepancy between the hypothesis and the data used to test it. An R value much in excess of 5 to 10 percent would be ground for suspicion. Jack D. Dunitz, *X-Ray Analysis and the Structure of Organic Molecules* 184 (1995). As calculated by Hursthouse himself, the R value for his test results was 18.74% and an astronomical 40.43% when he employed an alternative method of computation. And when Stephens adjusted the Hursthouse model to be consistent with his own data, the R value jumped to 41.51%. Stephens admitted that an R value over 40% is crap.

The ratio of observations to atomic parameters (spatial and thermal characteristics) is also used to assess the reliability of the type of analysis of chemical structure conducted by Hursthouse and Stephens. Hursthouse and Atwood agreed that a ratio of 10 to 1 is preferred and that any study in which the ratio of observations to parameters falls below about 5 to 1 is unreliable. From examination of Hursthouse's raw data

and his expert report, Atwood concluded that Hursthouse had used only 2,772 of the 12,301 observations he had collected, resulting in a ratio of observations to parameters of only 2.15 to 1. Although Hursthouse balked at Atwood's contention that he had used only 2,772 observations, he neither provided any support for his rejection of Atwood's contention nor quarreled with Atwood's estimate of a 2.15 to 1 observations-to-parameters ratio. Nor did he confute Atwood's testimony that the crystal on which Hursthouse performed his test was of an exceedingly small size and in fact below the minimum size recommended for study of organic compounds by [single crystal X-ray diffraction analysis, Hursthouse's method]. Atwood also testified that the crystal was of low quality. The significant problems with Hursthouse's experiment deprive his results of any probative value. (Atwood also complained about manipulations that Hursthouse had made in refining the data so that it would fit a polymeric model.)

Atwood testified that Stephens had had to alter Hursthouse's model of divalproex sodium in several ways in order to get it to match his powder X-ray diffraction data. One of these ways was by stretching the bonds between atoms. By stretching the bonds, Stephens weakened them, with the result that there was a break every seven units, suggesting an oligomer-which is to say that Stephens himself was offering evidence that supported Abbott! Even Hursthouse suggested that it was possible that the Nu-Pharm sample could be a series of oligomers. Atwood also questioned whether the samples on which Apotex's experts conducted their tests

are representative of the bulk material from which they were drawn.

One mustn't miss the forest for the trees. One must consider the evidence in its entirety, including Sherman's seeming indifference to patent law and injunctions and the pregnant failure of his experts to run their tests on the Abbott and original Apotex products. The evidence taken as a whole overwhelmingly favors Abbott.

All that Apotex is left to argue is that a contempt proceeding is an improper vehicle for determining infringement if expert evidence is presented. The Federal Circuit has never so held, but on the contrary in *Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc., supra,* 154 F.3d at 1349, approved the district court's decision to conduct a contempt proceeding in which expert evidence was presented. And it has explained that the need for expert evidence counsels against the contempt route only when the defendant has made a good-faith effort to comply with the injunction, *Arbek Mfg., Inc. v. Moazzam,* 55 F.3d 1567, 1570 (Fed.Cir.1995), which Apotex did not do. As Sherman made only minor modifications, unsupported by any scientific rationale, to a process that had generated a product previously adjudged infringing and enjoined, it behooved him to conduct scientific testing to determine whether his product was indeed not an oligomer and therefore not infringing. His failure to conduct any scientific testing and his cavalier disregard for judicial findings that the patent was valid and infringed by his original product, as well as his use of

Nu-Pharm as a stalking horse, were the antithesis of good faith.

Were I to hold that contempt proceedings were impermissible in this case, it would be difficult to imagine any pharmaceutical patent case in which a contempt proceeding was permissible. No judge is qualified to determine by looking at a heap of powder (as Apotex's attorneys invited me to do) whether a change in the process by which a chemical is made has altered the chemical structure of the product without scientific testing conducted by experts. If Apotex can elude a finding of contempt, enjoined infringers need make only a trivial change in the process by which their infringing product had been made and present shoddy scientific evidence that the new product is different. Such infringers would not even need to have a good faith belief that the changes in the process had resulted in a noninfringing product. They would scour the scientific community for new experts and new tests that gave the desired result and go from judge to judge arguing that what was in reality the same substance held to have infringed was actually noninfringing. Injunctions in pharmaceutical patent cases would be worthless and the Federal Circuit's characterization of contempt proceedings as a shield protecting the patentee against an infringer's flagrant disregard for court orders would be a sour joke. *Id.* at 1570.

Apotex insists quite rightly that attempting to invent around a valid patent is legitimate conduct. Indeed, one of the purposes of requiring that a patent explain in detail

how to make the patented product is to facilitate inventing around (and thus trim the economic consequences of the patent monopoly, as well as to facilitate greater innovation) by giving other inventors information that may enable them to figure out how they can create a product that does not infringe but that confers similar benefits on consumers. But the privilege of inventing around is not a privilege to violate an injunction against infringement by producing the identical product enjoined as a patent violation and defending such behavior by saying that the defendant was simply trying to invent around. Unreconciled to a binding judicial determination that the divalproex sodium product patented by Abbott is an oligomer, Apotex is determined to keep making divalproex sodium until new tests or new testers convince some judge somewhere of the soundness of an opinion that he is not even professionally competent to form.

The injunction has been violated. Should the violation continue, Apotex—a large, successful, and sophisticated enterprise-will be risking heavy sanctions for its willful disobedience of the injunction. For the present, however, it will suffice to extend the injunction to embrace the Nu-Pharm ANDA, *Conoco, Inc. v. Energy & Environmental Int'l, L.C., supra*, 460 F.3d 1349, 1365; the extended injunction is attached to this opinion.

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING AND REHEARING EN BANC DATED AND FILED DECEMBER 5, 2007

UNITED STATES COURT OF APPEALS
FEDERAL CIRCUIT

2007-1019

ABBOTT LABORATORIES,

Plaintiff-Appellee,

v.

TORPHARM, INC.,
APOTEX, INC., and APOTEX CORPORATION,

Defendants-Appellants.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellants, and a response thereto having been invited by the court and filed by the Appellee, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

Appendix C

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on December 12, 2007.

Circuit Judge Schall did not participate in the vote.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 12/05/2007

APPENDIX D — 35 U.S.C.A. § 271(e)

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit —

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2) —

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United

States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

* * * *

APPENDIX E — EXCERPTS FROM TRANSCRIPT OF PROCEEDINGS DATED AUGUST 30, 2006

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 97 C 7515

ABBOTT LABORATORIES, an Illinois corporation,

Plaintiff,

vs.

TORPHARM, INC., a Canadian corporation,
APOTEX, INC., a Canadian corporation, and
APOTEX CORP., a Delaware corporation,

Defendants.

Chicago, Illinois
August 30, 2006
9:00 a.m.

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE
RICHARD A. POSNER

* * *

MS. MAZZOCHI: Well, sure. But we should be able to obtain — develop evidence to rebut that if that's what's going to be dispositive on this point.

THE COURT: But I haven't heard any evidence.

MS. MAZZOCHI: Well, your Honor, because I don't — me personally, and on behalf of Apotex, there hasn't been physical time to rebut this. I mean, quite frankly, the — I mean, Abbott could have brought this up back in November, and for whatever reason, they chose to sit on it. And they sat on it until they saw the crystal structure results in the Nu-Pharm case, and then all of a sudden, they didn't want to be in front of Judge Pallmeyer anymore. Then they said, "We want to come back before Judge Posner." Okay. Fine.

And to me, it's clear, Judge, they wanted to do that because, you know — and we're realizing here, they wanted to basically say, you know, this is close enough to this, and, you know, we're going to do the same tests and what have you. And that's fine. And I understand their tactics. But I should be given the opportunity, if truly what's going to be dispositive on this issue is, is the TorPharm product, you know, chemically or whatever the same, you know, I don't think that this type of truncated proceeding is the right way to handle it. I think that we should be allowed to develop evidence. I think that I should certainly be allowed to test how great Dr. Atwood's data is or is not before — before Apotex should be getting enjoined.

And I can appreciate, your Honor, that you're saying, "Well, hey, you should have done this several months ago," but to date, the activities that Apotex has engaged in, they don't qualify as acts of infringement. So, you

know, if — and if — you know, and if you want to talk about what does Nu-Pharm think they've got, Nu-Pharm thinks they've got a non-infringing product.

And the act of infringement that is at issue is did you submit a paragraph 4 certification saying that your ANDA was going to make an infringing product? That's the issue that's present in the Nu-Pharm case. I think the answer to that has been no, because Nu-Pharm believes it has the tests that show its Nu-Pharm ANDA product is non-infringing.

And while I understand that Abbott wants to say, "Oh, you're just making the same old stuff" Glaxo made that same argument in the NovaPharm case, "NovaPharm, we think you've changed your process conditions and now you're getting polymorph Form 1 instead of polymorph Form 2, but we still think you've got that Form 2 in there, so you're still infringing."

They got to do discovery. They got to do a trial on the merits. They got to put on, you know, experts on these issues. And I don't see why we shouldn't be given that same opportunity to do that, you know, particularly if this Court, as it indicated it might, is going to, you know, take the case from Judge Pallmeyer. And if that's going to be the issue that the Court cares about, we are perfectly happy to respond to that —

* * *

MS. MAZZOCHI: Well, your Honor, it appears that any further examination that I would make of Dr. Atwood is not going to prove fruitful because to the extent I try to question him —

THE COURT: Well, I gather you're not prepared to challenge him about — about whether he somehow did something different this time which might have — from what he did last time that might explain why, in his various tests, Nu-Pharm and TorPharm look alike.

MS. MAZZOCHI: Well, part of the reason why I'm hampered in those efforts, your Honor, is because I don't know all the details about what Dr. Atwood did. I mean, there's not a lot of backup information for what he did. I certainly don't have any information about how the SSCI people handled samples or did whatever.

So, if it becomes a question of, you know, your saying that from me, I need to provide either my — you know, I either don't get to take discovery done before or I need to provide my own counter examples, truly, your Honor, I can't order those tests up and say, "Please have them here in 20 days."

THE COURT: So, you're saying that to do proper cross-examination of Dr. Atwood, you would need more discovery or information or something?

MS. MAZZOCHI: Right.

* * *

THE COURT: Okay. Now, there's one legal question I'd like you to address. So, the KSM question — the KSM opinion states that to make a finding of contempt, the judge must find the evidence is clear and convincing, but you're not actually asking me to find Apotex in contempt, is that correct?

MR. REIDY: That's correct, Judge. We haven't gone as far as to ask — we believe that it's more than satisfied under KSM, but —

THE COURT: So, my legal question is whether I have to find by clear and convincing evidence that these are the same products, even though I'm not actually going to find contempt or enter a contempt sanction, but just make a ruling on the application — or applicability of the second paragraph of the injunction.

MR REIDY: We'll address that in our brief, Judge.

MS. MAZZOCHI: Thank you, your Honor.

THE COURT: Anything further?

MS. MAZZOCHI: No, your Honor.

* * * *

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FILED
APR 7 - 2008
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 07-912

IN THE

Supreme Court of the United States

APOTEX, INC. and APOTEX CORPORATION,

Petitioners,

v.

ABBOTT LABORATORIES,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit correctly ruled that, even where no contempt sanction could properly be imposed against petitioners, the district court did not abuse its discretion by conducting proceedings to examine whether its prior injunction had been violated, by making factual findings incident to that inquiry, and by modifying its injunction according to those findings to prohibit petitioners' new infringing activities, which involved using another corporation as a "subterfuge" and "stalking horse" for performing the same activities previously enjoined.

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

There is no public corporation that owns 10% or more of the stock of respondent Abbott Laboratories.

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BRIEF IN OPPOSITION

Respondent Abbott Laboratories respectfully requests that this Court deny the petition for a writ of certiorari for three basic and fundamental reasons:

First, the decision below presents no conflict among the circuits, and is perfectly in keeping with this Court's decisions. The Federal Circuit did no more than follow the sound and established law recognizing that a trial judge has the inherent authority to modify an injunctive order where the facts warrant such an action, regardless of whether a contempt sanction ultimately is imposed for violation of the original order. Contrary to petitioners' suggestion, the modification of an injunction, and the factual findings that undergird such a modification, are not "contempt remedies" that are forbidden if unaccompanied by an ultimate contempt sanction.

Second, once petitioners' misconception of the law is cleared away, all that remains is the Federal Circuit's decision—rendered after a decade of fierce litigation between the parties, including three appeals—that the trial court did not abuse its discretion in modifying an injunction to capture petitioners' proposed infringing product, where the record established that the product proposed to be manufactured under the new Abbreviated New Drug Application (ANDA) was identical to an ANDA product previously adjudged infringing and enjoined after a trial. Such a factbound decision scarcely warrants this Court's attention.

Third, there is little, if anything, at stake here. The patents-in-suit have expired, and this matter unquestionably will become moot no later than July 30, 2008, when Abbott's statutory period of pediatric

exclusivity comes to an end. Even setting aside the other significant reasons to deny review, the procedural posture and imminent mootness of the dispute renders this case an exceedingly poor vehicle to resolve the questions presented.

STATEMENT

Petitioners' recitation of the facts is highly selective, and in many respects incomplete and materially inaccurate. The facts germane to the issues presented to this Court are as follows:

I. Abbott's Patents

Abbott owns two patents that cover divalproex sodium, the active ingredient in Depakote®—a product widely prescribed in treatment of epilepsy, bipolar disorder, and migraine headaches. The patents have been adjudged valid and enforceable. *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1381 (Fed. Cir. 2002) (*Abbott II*). Both patents expired on January 29, 2008. Having completed extensive pediatric studies, Abbott has been awarded an additional period of regulatory exclusivity by the U.S. Food and Drug Administration (FDA) that will prevent final approval of any generic divalproex sodium products until after July 29, 2008. *See* 21 U.S.C. § 355a(c)(1)(B).

II. Litigation History

A. The Apotex ANDA Litigation.

In April 1997, petitioners (through a division formerly known as TorPharm, Inc.) submitted Abbreviated New Drug Application No. 75-112 (the Apotex ANDA) to the FDA, seeking approval to market a generic copy of Depakote® prior to the expiration of Abbott's patents. *Abbott Labs. v.*

TorPharm, Inc., 156 F. Supp. 2d 738, 739-40 (N.D. Ill. 2001) (*Abbott I*); *Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043, 1044 (N.D. Ill. 2004) (*Abbott III*). Abbott sued for patent infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and secured summary judgment on all issues before the United States District Court for the Northern District of Illinois. *See Abbott I*, 156 F. Supp. 2d at 747-49.

In the first of three appeals to the Federal Circuit, the court upheld summary judgment in Abbott's favor as to all issues save one, remanding the case for trial with respect to infringement of a single claim limitation (whether petitioners' product was an "oligomer"—a molecule comprised of a relatively small number of repeating units joined together). *See Abbott II*, 300 F.3d at 1381.

After a trial on the merits, Circuit Judge Richard A. Posner, sitting by designation in the district court, ruled that petitioners' product was infringing. *See Abbott III*, 309 F. Supp. 2d at 1054. On March 31, 2004, he issued an injunction order directing that:

> [Defendants], and their respective affiliates, successors in interest, and assigns are enjoined from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing within the United States, or from importing such product into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received final approval from FDA to market generic divalproex sodium.
>
> The effective date for any approval by FDA of ANDA No. 75-112, *or any other application*

> *concerning defendants' generic divalproex sodium which the Court has found to be infringing*, shall be no earlier than January 29, 2008, the date of expiration of Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326.

Pet. App. 4a-5a (emphasis added). In the second appeal, the Federal Circuit affirmed in all respects. *Abbott Labs. v. TorPharm, Inc.*, 122 F. App'x 511 (Fed. Cir. 2005) (*Abbott IV*).

B. The Nu-Pharm ANDA Litigation.

1. Petitioners Enlist Nu-Pharm In Their Effort To Avoid The 2004 Injunction.

Even before the conclusion of the trial before Judge Posner, petitioners feared a loss and therefore put in motion plans to submit a new ANDA, hoping to provoke new litigation against Abbott and to secure different rulings from a new judge. *Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831, 835 (N.D. Ill. 2006) (*Abbott V*). Petitioners' CEO, Barry Sherman, revised the manufacturing processes for making the divalproex sodium product that was adjudged to be infringing and enjoined. Despite Sherman's express belief that the revised product might be even "more likely to infringe" Abbott's patents than the product already enjoined, petitioners did not commission a single scientific test to determine whether the revisions to the manufacturing process actually resulted in a different product. Pet. App. 34a. Nevertheless, within weeks of the 2004 injunction order, Sherman directed that his revised product be submitted for approval in a new ANDA.

However, there remained the question of who would actually be the applicant for the new ANDA.

Apotex, the applicant for the earlier ANDA, is the largest generic pharmaceutical manufacturer in Canada, and among the largest in the world. *See* Pet. App. 43a. The company admittedly had no need for outside assistance to prepare or submit the new ANDA, nor to market the revised product were it to be approved by FDA. Because of the existing injunction, however, Apotex was concerned about filing the new ANDA in its own name. Instead, Apotex determined that the new ANDA would be submitted in the name of Nu-Pharm, Inc.—a six-person company formerly owned by Apotex, and whose sole business is to market and sell re-labeled Apotex products in Canada. Pet. App. 30a-31a.

Although petitioners claim that Nu-Pharm "took on the R&D costs" associated with the revised product as part of some arrangement with petitioners (Pet. 8), that is false. Nu-Pharm's president has sworn that his company's only role in this process was (i) to receive ANDA documents prepared by petitioners, print them on Nu-Pharm letterhead, and sign as instructed by petitioners; and (ii) to fund new litigation against Abbott. C.A. App. A2161, 2164-65, 3375-80, 3899, 3902-04. Nu-Pharm thus served only as a nominal ANDA applicant: It has no ownership rights in the product; had nothing to do with the development or biotesting of the product; and did not participate in any way (other than printing and signing) in the preparation or submission of the ANDA. Indeed, Nu-Pharm was not even told that it would serve as the ANDA applicant until months after the decision was made at Apotex. C.A. App. A2159-60, 2177, 3527.

There is no contract or license between Nu-Pharm and Apotex relating to this product (C.A. App. A2110-11, 2163), despite the fact that, had it been approved, it would have been the first generic version of a drug (Depakote®) with annual sales revenues topping $1 billion. When asked why petitioners would even consider sharing this opportunity with Nu-Pharm, Apotex CEO Sherman testified that, "I am giving them money. They are taking on the litigation [against Abbott], and they are earning it." Because Apotex, not Nu-Pharm, owns the product, Sherman reasoned that, if the product were ever marketed, "we will get our profit out of it, anyway." C.A. App. A2108.

2. Acting Through Nu-Pharm, Apotex Succeeded In Provoking New Litigation With Abbott.

In March 2005, petitioner Apotex Corp. submitted (on behalf of Nu-Pharm) ANDA No. 77-615 (the Nu-Pharm ANDA) to the FDA, seeking approval of Apotex's "redesigned" divalproex sodium product. The Nu-Pharm ANDA included a Paragraph IV certification, *see* 21 U.S.C. § 355(b)(2)(A)(iv), attesting that the product described in the ANDA would not infringe Abbott's patents, and thus should be approved by FDA prior to the patents' expiry.

Petitioners state that Nu-Pharm made an "independent assessment" of infringement prior to submitting that certification to FDA. Pet. 8. This, too, is false. The certification was prepared by Apotex, and Nu-Pharm's president, Richard Benyak, was directed to sign it. Benyak has testified that neither he nor anyone at Nu-Pharm knew anything about the science underlying the product, nor

whether it in fact infringed Abbott's patents, and they commissioned no tests to find out. Instead, Benyak signed the certification simply because "an ANDA wouldn't be filed if it was obviously an infringing product, to my way of thinking." C.A. App. A2167, 2857. For the certification of non-infringement, as with everything else, Nu-Pharm relied completely on Apotex. Yet, despite its own concern that the revised product might be even "more likely to infringe" than the earlier, enjoined product (C.A. App. A2091, 2096), Apotex commissioned no scientific testing to support the assertions of non-infringement in the Paragraph IV certification before presenting it to Nu-Pharm for signature. C.A. App. A2112, 2088.

As required by statute, Nu-Pharm's counsel (the same counsel representing petitioners here and in *Abbott I, II, III, IV, V,* and *VI*) sent notice of the Nu-Pharm ANDA to Abbott. The notice made no mention of Apotex. Under the Hatch-Waxman Act, Abbott had 45 days from receipt of this notice to file a lawsuit to protect its patent rights, and it did so on June 24, 2005. *See Abbott V*, 455 F. Supp. 2d at 835 (referring to *Abbott Labs. v. Nu-Pharm, Inc.*, No. 05 C 3714 (N.D. Ill.) (the Nu-Pharm Litigation)). The suit was assigned to Judge Rebecca Pallmeyer. *Id.* When Nu-Pharm produced the ANDA in discovery, Abbott learned for the first time that Apotex was involved, though its role was described in the ANDA merely as a contract manufacturer. Abbott amended its complaint in the Nu-Pharm Litigation to add claims against petitioners for direct and induced infringement. *See Abbott Labs. v. Apotex, Inc.*, 503 F.3d 1372, 1377 (Fed. Cir. 2007) (*Abbott VI*). Petitioners moved to dismiss, insisting that the Nu-

Pharm ANDA "ha[d] nothing to do with [them]." C.A. App. A3551. That motion remains pending.

C. The Enforcement Proceedings Before Judge Posner And Subsequent Appeal.

Through its own scientific testing, Abbott confirmed that the product described in the Nu-Pharm ANDA is identical to that previously adjudged infringing and enjoined by Judge Posner. Then, in July 2006, Abbott conducted the depositions of Apotex CEO Sherman and Nu-Pharm president Benyak, where Abbott learned for the first time the full nature of Apotex's control of all aspects of the Nu-Pharm ANDA—including the fact that the Nu-Pharm ANDA product does not belong to Nu-Pharm at all, but is instead owned outright by Apotex. Armed with its scientific testing and these critical admissions, Abbott returned to Judge Posner and asked that he enforce the original 2004 injunction order (which, by its terms, barred FDA approval of any ANDA concerning the same infringing product) against the Nu-Pharm ANDA. Pet. App. 26a-27a, 31a-32a. Nu-Pharm elected to have its interests represented by petitioners in the enforcement proceedings (and the lawyers were the same in any event, since the two companies then shared, and continue to this day to share, the same counsel).

After briefing from both sides, Judge Posner held a hearing on August 30, 2006. Pet. App. 32a. On October 6, 2006, Judge Posner granted Abbott's motion and extended the injunction order to cover the Nu-Pharm ANDA. Of note, the court found that "[t]he product for which Nu-Pharm filed the ANDA had been developed by Apotex, is owned by it, and, as Sherman has testified, we [Apotex] will get our profit

out of it, anyway." Pet. App. 30a-31a. Apotex's choice of Nu-Pharm to file the ANDA was, the court concluded, merely "a subterfuge intended to give Apotex a crack at another district judge, who might, in an infringement suit by Abbott, conclude that it was a different, and noninfringing, product from the one I had enjoined." Pet. App. 31a. As to the question of infringement, the court found that "there is no difference at all" between the Nu-Pharm ANDA product and the one previously found infringing and enjoined in 2004 (Pet. App. 37a), and that the fresh infringement evidence presented at the hearing relating to the redesigned "Nu-Pharm" product (including testimony and studies from three experts for petitioners) "overwhelmingly favor[ed] Abbott." Pet. App. 41a.

Based upon these findings, Judge Posner concluded that "[t]he injunction has been violated. Should the violation continue, Apotex—a large, successful, and sophisticated enterprise—will be risking heavy sanctions for its willful disobedience of the injunction. *For the present, however, it will suffice to extend the injunction to embrace the Nu-Pharm ANDA.*" Pet. App. 43a (emphasis added). The court thus revised its original injunction order so as to make clear that "[t]he effective date of any approval by FDA of ANDA Nos. 75-112 [the Apotex ANDA] and 77-615 [the Nu-Pharm ANDA], or any other application concerning defendants' generic divalproex sodium which the Court has found to be infringing, shall be no earlier than January 29, 2008, the date of expiration of Abbott's [patents]." C.A. App. A2.

In the third appeal, the Federal Circuit ruled that petitioners were not in contempt of the 2004

injunction, because that order did not provide "explicit notice" to petitioners that they were prohibited from using another company as a "straw party" to submit a new ANDA for a redesigned, but equally infringing, product. Pet. App. 19a-20a. Even absent an ultimate sanction of contempt, however, the Federal Circuit recognized the trial court's authority to conduct proceedings to examine whether its earlier injunction had been violated, to make factual findings, and to modify the original injunction to address new infringing activity. *Id.* Based upon the detailed factual record, the Federal Circuit ruled that the district court had not abused its discretion in finding the Nu-Pharm ANDA product to be infringing and in modifying the 2004 injunction to bar FDA approval of that ANDA until after the expiry of Abbott's patents. Pet. App. 14a-16a. Petitioners' subsequent request for panel and/or en banc rehearing was denied. Pet. App. 44a-45a.

D. Nu-Pharm Sues The FDA.

On January 14, 2008, just days after filing this petition for a writ of certiorari, petitioners' counsel (this time ostensibly on behalf of Nu-Pharm) instituted an action in the U.S. District Court for the District of Columbia against the FDA and certain senior officials, followed immediately by a motion for a temporary restraining order or preliminary injunction, demanding immediate approval of the Nu-Pharm ANDA prior to the expiry of Abbott's patents. With no notice to Abbott, Nu-Pharm urged the D.C. court to find that it was arbitrary and capricious for FDA to follow Judge Posner's modified 2006 injunction (by this time upheld by the Federal

Circuit), and to order the agency to disregard that injunction and immediately approve the ANDA.

When Abbott learned of this action from FDA, it immediately sought leave to intervene and filed papers opposing the motion for emergency injunctive relief. After a hearing, the D.C. court denied the motion and declined to exercise any further jurisdiction over the case. Nu-Pharm is currently seeking review of that decision before the U.S. Court of Appeals for the D.C. Circuit.

REASONS FOR DENYING THE WRIT

1. The decision of the Federal Circuit was correct, and cannot colorably be alleged to conflict with any decision of any other court of appeals, or of this Court. The crux of petitioners' argument is that a district court in a patent dispute, faced with the contention that a "redesigned" product violates a previously-entered injunctive order, has only two choices: impose the extreme sanction of contempt on the alleged offender, or do nothing at all. Thus, petitioners claim that when the Federal Circuit ruled that petitioners were not technically in contempt of the 2004 injunction order, it was automatically required to vacate the modified injunction order entered by the district court in 2006 and to wash away all of the district court's underlying factual findings. The Federal Circuit correctly rejected this "contempt or nothing" approach.

As the Court of Appeals recognized (Pet. App. 12a-13a & n.3), the problem with petitioners' logic is that it ignores well-established precedent instructing that whether to hold summary contempt proceedings in a patent dispute, and whether to impose a contempt sanction at the culmination of such proceedings, are

two separate inquiries. *See KSM Fastening Sys., Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1525 (Fed. Cir. 1985) ("(1) when contempt proceedings will be entertained, and (2) when contempt will be found . . . are separate questions . . . "); *see also Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 154 F.3d 1345, 1349-50 (Fed. Cir. 1998) (same). Before ever considering whether to impose a contempt sanction, the trial court first "must address whether a contempt hearing is an appropriate forum for adjudging whether an allegedly redesigned product is infringing." Pet. App. 12a. This threshold determination requires the trial court to weigh the evidence and make a factual finding as to whether there is "'more than a colorable difference' between the accused product and the adjudged infringing product." *Id.* (quoting *KSM*, 776 F.2d at 1532). If such colorable differences are found to exist, then there are "'substantial open issues with respect to infringement,'" and a new lawsuit should be pursued, rather than summary contempt proceedings. Pet. App. 12a (quoting *KSM*, 776 F.2d at 1532); *see also Additive Controls*, 154 F.3d at 1349-50. Where the trial court determines that there are no "colorable differences," however, it can move forward in summary proceedings to adjudge whether the accused, redesigned product is infringing. Pet. App. 12a. If infringement is found by clear and convincing evidence, the trial court may, but certainly is not obligated to, impose a contempt sanction. *See* Pet. App. 16a.

The multi-step process carefully limned by the Federal Circuit in *KSM* and *Additive Controls* necessarily presupposes that there are some cases, like this one, where the facts demonstrate that

contempt *proceedings* are appropriate, even if an ultimate *finding of contempt* is not. In such cases, where new activity infringes the patents supporting a prior injunction, but does not come directly within the scope of that injunction, it is well recognized that the trial court can fashion a remedy of something less than contempt following summary proceedings. Most notably, a court may extend the prior injunction to clarify that it applies to the new infringing activity. *See Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1365 (Fed. Cir. 2006) (holding that, where an accused infringer's purportedly redesigned product was effectively no different from the product previously adjudged infringing, "a court may properly extend the injunction to the new device . . . ." without finding contempt); *Decade Indus. v. Wood Tech., Inc.*, 145 F. Supp. 2d 1075, 1076-77 (D. Minn. 2001) (following *KSM* and finding "redesigned" product to be infringing after summary proceedings, but not imposing contempt sanctions); *cf. Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 380 (1992) ("sound judicial discretion may call for the modification of the terms of an injunctive decree if the circumstances, whether of law or fact, obtaining at the time of issuance have changed, or new ones have since arisen") (internal quotation marks omitted). The Federal Circuit properly declined petitioners' invitation to strip trial judges of this longstanding equitable authority to modify injunctions absent a contempt sanction, a decision not in conflict with any precedent from this or other courts, or with the Hatch-Waxman Act itself.

a. Petitioners rely principally on this Court's 1885 decision in *California Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609. *Molitor* was cited by the

dissent below for the general proposition that the "[p]rocess of contempt is a severe remedy, and should not be resorted to where there is fair ground of doubt as to the wrongfulness of the defendant's conduct." Pet. App. 21a (dissenting opinion) (quoting *Molitor*, 113 U.S. at 618). As the majority correctly rejoined, however, "[i]in patent infringement cases, this inquiry has been restated as whether there is a colorable difference between the accused and adjudged devices." Pet. App. 12a n.3 (citing *KSM*, 776 F.2d at 1536). Moreover, the dissent "d[id] not identify any colorable difference between the adjudged and accused products, and thus seems to agree that there was no 'fair ground of doubt' as to the lower court's determination of infringement." Pet. App. 13a n.3. The decision below thus comports with *Molitor*, and petitioners cannot tenably claim otherwise. (Indeed, they never cited *Molitor* in their briefs or argument before the panel.)

The remaining cases proffered by petitioners—which were likewise not cited by petitioners in their briefs or arguments before the Court of Appeals—are even less helpful to their cause. None of them even comes close to addressing the question whether a court may modify an injunction in lieu of finding a party in contempt. *See, e.g., Cooke v. United States*, 267 U.S. 517, 532 (1925) (addressing process due to a lawyer accused of direct contempt of court); *Ex parte Fisk*, 113 U.S. 713, 726 (1885) (lower court lacked jurisdiction to issue the underlying order from which contempt was claimed and was therefore "equally without authority to enforce those orders by process for contempt"); *Hicks v. Feiock*, 485 U.S. 624, 640-41 (1988) (vacating judgment of contempt and remanding to allow the lower court to make

additional factual findings and consider legal arguments as to whether the contempt at issue was civil or criminal); *Fonar Corp. v. Deccaid Servs., Inc.*, 983 F.2d 427, 429 (2d Cir. 1993) (vacating a contempt sanction because the underlying order was unclear and ambiguous; the court left intact the underlying factual findings); *United States v. Spectro Foods Corp.*, 544 F.2d 1175, 1182 (3d Cir. 1976) (vacating contempt sanction where underlying injunctive order was invalid); *Imageware, Inc. v. U.S. W. Commc'ns*, 219 F.3d 793, 797 (8th Cir. 2000) (reversing contempt finding because the underlying protective order was ambiguous); *Proctor v. State Gov't of N.C.*, 830 F.2d 514, 521-22 (4th Cir. 1987) (vacating contempt order and remanding for factfinding where trial court failed to conduct an independent factfinding in the first instance); *Karaha Bodas Co. v. Perusahaan Pertambangan Minyak Dan Gas Bumi Negara*, 335 F.3d 357 (5th Cir. 2003) (contempt cannot lie where underlying injunction is invalid); *Collins v. Barry*, 841 F.2d 1297, 1300 (6th Cir. 1988) (contempt order was inappropriate where underlying law did not apply to plaintiff); *Ferrell v. U.S. Dep't of Hous. & Urban Dev.*, 186 F.3d 805, 813-14 (7th Cir. 1999) (intervening change in underlying law rendered contempt inappropriate); *FTC v. Enforma Natural Prods., Inc.*, 362 F.3d 1204, 1219 (9th Cir. 2004) (vacating one of two injunction orders because the trial court unilaterally altered a stipulated consent decree without giving the parties a chance to object); *FTC v. Kuykendall*, 371 F.3d 745, 759, 762 (10th Cir. 2004) (vacating contempt sanction based upon deficient factual support in the record); *Shepherd v. Am. Broad. Cos.*, 62 F.3d 1469, 1473-74 (D.C. Cir. 1995) (addressing the propriety of default judgment

as a discovery sanction); *United Elec., Radio & Mach. Workers of Am. v. 163 Pleasant St. Corp.*, 960 F.2d 1080, 1099 (1st Cir. 1992) (vacating contempt sanction because the underlying order was invalid for lack of jurisdiction); *Doe v. Bush*, 261 F.3d 1037, 1063-64 (11th Cir. 2001) (reversing contempt sanction where findings upon which sanction was based were legally or factually incorrect, but adding that "under appropriate circumstances and after the proper procedures have been followed, the original injunction in this case might have been modified to address the problems"). None of these decisions conflicts directly, let alone in principle, with the Court of Appeals' decision here.

b. Similarly, neither the Hatch-Waxman Act, nor the policies underlying it, conflicts in any way with the Federal Circuit's decision. Indeed, the authority to summarily modify an injunction is *especially* necessary in Hatch-Waxman Act litigation where, by statute, only injunctive relief is typically available. *See* 35 U.S.C. § 271(e)(4). The district court put it aptly: if petitioners' contrary position were correct, "[i]njunctions in pharmaceutical patent cases would be worthless and the Federal Circuit's characterization of contempt proceedings as a shield protecting the patentee against an infringer's flagrant disregard for court orders would be a sour joke." Pet. App. 42a. The facts of *this* case make that conclusion all the more apt, for petitioners used a "stalking horse" to submit a "new" ANDA covering the same product previously enjoined. As the Court of Appeals recognized,

> [s]ince neither infringement nor the inapplicability of the injunction to the accused conduct was

> doubtful, summary determination before the district court was appropriate. A different rule would require a defendant to participate in full litigation, even though he could be absolved summarily of contempt liability when, as here, there is no doubt about the issue at hand. Such a rule would serve neither defendant's due process interests nor judicial economy.

Pet. App. 13a n.3. The Act (like patent law generally) may promote good-faith efforts to design around patents, but that is *not* what happened here. To the contrary, the district court found that Apotex CEO Sherman's "failure to conduct any scientific testing and his cavalier disregard for judicial findings that the patent was valid and infringed by his original product, as well as his use of Nu-Pharm as a stalking horse, were the antithesis of good faith." Pet. App. 41a-42a. Nothing in the Act is designed to reward such "contumacy." *See* Pet. App. 35a.

2. Casting aside petitioners' "contempt or nothing" approach, all that remains is a challenge to the Federal Circuit's treatment of the underlying fact-finding by the district court. In particular, the Federal Circuit held that the district court did not abuse its discretion in holding summary contempt proceedings (based upon its finding that there was "no difference at all" between the product described in the Nu-Pharm ANDA and the product previously enjoined), and did not clearly err in finding, by clear and convincing evidence, that the "redesigned" Nu-Pharm ANDA product infringed Abbott's patents. Pet. App. 14a-15a. The Federal Circuit's decisions in this regard are inextricably linked to the detailed factual record developed before the trial court—

including extensive briefing, scientific documents, deposition testimony, expert reports, and live testimony of numerous scientific experts for both sides. Such hopelessly factbound determinations are inappropriate fodder for this Court. *See, e.g., United States v. Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

3. Finally, the unique posture of this case makes it an exceedingly poor vehicle for certiorari. For one, it is the rare case where, as here, an enjoined defendant employs a "stalking horse" in bad faith in order to avoid the terms of an injunction, and so this case would be an exceptionally poor vehicle for addressing the question presented.

More critically, however, is the fact that there is so little at stake here. The patents-in-suit already have expired, so Abbott can no longer sue any entity for patent infringement. The only thing that animates the case at this point is the fact that, having completed important studies showing the efficacy of Depakote® in children, Abbott has been awarded by FDA a period of *regulatory* exclusivity extending six months from the expiry of its patents, during which time no application for a generic divalproex sodium product can be approved by FDA. *See* 21 U.S.C. § 355a(c)(1)(B). That pediatric exclusivity period will expire on July 29, 2008 (barely more than three months from the filing of this brief), and that expiration will open the door for generic approvals from all proper applicants, and render this case unquestionably moot. Thus, even were the Court otherwise inclined to examine the "contempt or nothing" standard advocated by petitioners, which it

need not do, it surely should not undertake this task in a matter where so little is at stake at this point.

* * * *

In light of the factbound nature of this case, the absence of any conflict within or among the circuit courts, the correctness of the decision below, and the fact that so little is at stake at this point, the petition presents no colorable basis for review.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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